

Gene Technology Act 2000

No. 169, 2000

This future law compilation was prepared on 6 August 2024 taking into account amendments made by the **Gene Technology Amendment Bill 2024**.

The date of commencement for the incorporated amendments was unknown at the time of preparation.

Prepared by the Office of Parliamentary Counsel, Canberra

About this compilation

This compilation

This is a future compilation of the *Gene Technology Act 2000* that shows the expected text of the law as amended by the Gene Technology Amendment Bill 2024.

The notes at the end of this compilation (the *endnotes*) include information about amending laws and the amendment history of provisions of the future compilation.

Future amendments

The details of expected future amendments incorporated into the text, that have not yet commenced are underlined in the endnotes.

Any future amendments that are included in the endnotes are underlined.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Preliminary Part 1

Section 1

An Act to regulate activities involving gene technology, and for related purposes

Part 1—Preliminary

1 Short title

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

2 Commencement

- (1) Sections 1 and 2 of this Act commence on the day on which this Act receives the Royal Assent.
- (2) Subject to subsection (3), the other provisions of this Act commence on a day or days to be fixed by Proclamation.
- (3) If a provision of this Act does not commence under subsection (2) within 6 months after the day on which this Act receives the Royal Assent, it commences on the first day after the end of that period.

3 Object of Act

The object of this Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

4 Regulatory framework to achieve object

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

(aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation; and

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Section 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 GM products.

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

5 Nationally consistent scheme

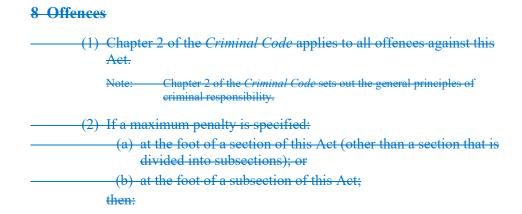
It is the intention of the Parliament that this Act form a component of a nationally consistent scheme for the regulation of certain dealings with GMOs by the Commonwealth and the States.

6 Act to bind the Crown

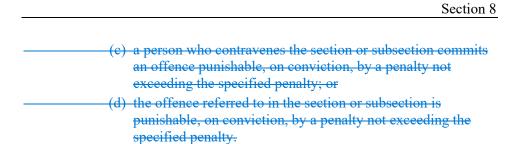
- (1) This Act binds the Crown in each of its capacities.
- (2) Nothing in this Act renders the Crown liable to be prosecuted for an offence.

7 External Territories

This Act extends to every external Territory.



Preliminary Part 1



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Part 2 Interpretation and operation of ActDivision 1 Simplified outline

Section 9

Part 2—Interpretation and operation of Act

Division 1—Simplified outline

9 Simplified outline

The following is a simplified outline of this Part:

This Part contains the definitions used in this Act.

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

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

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

Interpretation and operation of Act Part 2
Definitions Division 2

Section 10

Division 2—Definitions

10 Definitions

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

Account means the Gene Technology Account established by section 129.

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

aggravated contravention has the meaning given by section 35A.

aggravated offence has the meaning given by section 35 section 38.

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

authorisation requirements, for a notifiable dealing, has the meaning given by subsection 75(3).

authorised compliance officer means:

- (a) the Regulator; or
- (b) an authorised inspector.

authorised GMO dealing has the meaning given by section 31A.

authorised inspector means a person appointed as an authorised inspector under section 140.

business day means a day that is not a Saturday, a Sunday, a day specified in the regulations or a public holiday in the Australian Capital Territory.

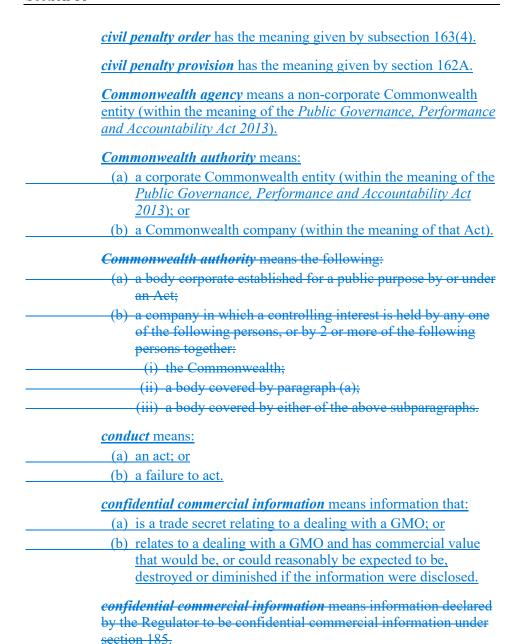
CCI is short for confidential commercial information.

certification, in relation to a facility, means the certification of a facility to a particular containment level under section 84.

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Part 2 Interpretation and operation of ActDivision 2 Definitions

Section 10



Interpretation and operation of Act Part 2
Definitions Division 2

Section 10

consideration period, for an application to which Division 1A of Part 12 applies, has the meaning given by section 178F.

Note: Section 178A sets out the applications to which Division 1A of Part 12 applies.

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

corresponding State law has the meaning given by section 12.

CSC (short for Commonwealth Superannuation Corporation) has the same meaning as in the *Governance of Australian Government Superannuation Schemes Act 2011*.

<u>damage</u>, in relation to data, includes damage by erasure or corruption of, or loss of access to, data, or the addition of other data.

<u>data storage device</u> has the same meaning as in the *Online Safety* <u>Act 2021.</u>

deal with, in relation to a GMO, has the meaning given by section 12A.

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

- (a) conduct experiments with the GMO;
- (b) make, develop, produce or manufacture the GMO;
- (c) breed the GMO;
- (d) propagate the GMO;
- (e) use the GMO in the course of manufacture of a thing that is not the GMO;
- (f) grow, raise or culture the GMO;
- (g) import the GMO;
- (h) transport the GMO;
- (i) dispose of the GMO;

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Part 2 Interpretation and operation of ActDivision 2 Definitions

Section 10

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

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

emergency dealing determination means a determination in force under section 72B.

entrusted person means a person who is, or was:

- (a) the Regulator; or
- (b) a member of the staff assisting the Regulator as mentioned in section 133; or
- (c) a person engaged as a consultant under section 134; or
- (d) a seconded officer made available to the Regulator under section 135; or
- (e) a person acting under the direction or authority of the Regulator.

environment includes:

- (a) ecosystems and their constituent parts; and
- (b) natural and physical resources; and
- (c) the qualities and characteristics of locations, places and areas.

Environment Minister means the Minister responsible for environment and conservation.

equipment includes electronic equipment.

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

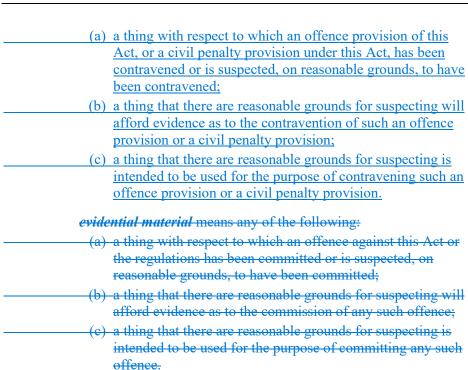
evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

evidential material means any of the following:

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Section 10



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

- (a) a building or part of a building;
- (b) a laboratory;
- (c) an aviary;
- (d) a glasshouse;
- (e) an insectary;
- (f) an animal house;
- (g) an aquarium or tank.

gene technology has the meaning given by section 12B.

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

- (a) sexual reproduction; or
- (b) homologous recombination; or

Gene Technology Act 2000

Part 2 Interpretation and operation of ActDivision 2 Definitions

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2	ection	

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

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

<u>Committee</u> means the Gene Technology Ethics and Community
Consultative Consultative Consultative established by section 106.

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

genetically modified organism has the meaning given by section 12C.

genetically modified organism means:

- (a) an organism that has been modified by gene technology; or
- (b) an organism that has inherited particular traits from an organism (the *initial organism*), being traits that occurred in the initial organism because of gene technology; or
- (c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

- (d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
- (e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

GMO means a genetically modified organism.

GMO licence means a licence issued under section 55.

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GMO permit means a permit issued under section 72AD.

GMO Register means the GMO Register established by section 76.

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

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

inadvertent, in relation to the possession of a GMO by person, means:

- (a) the person did not know the GMO was a GMO when it came into their possession; or
- (b) the person did not know the GMO had come into their possession when it came into their possession.

inadvertent dealings application means an application for a GMO licence to authorise dealings:

- (a) with a GMO that has come into the possession of the applicant inadvertently; and
- (b) for purposes limited to, and incidental to, one or more of the following:
 - (i) disposing of the GMO (which includes destroying the GMO or rendering the GMO non-viable):
 - (ii) exporting the GMO.

inadvertent dealings application means an application for a GMO licence to which Division 3 or 4 of Part 5 does not apply because of the operation of section 46A or 49.

Institutional Biosafety Committee means a committee established as an Institutional Biosafety Committee in accordance with <u>the rules underwritten guidelines issued by the Regulator under section 98.</u>

investigation powers has the meaning given by sections 152A, 152B and 152C.

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Part 2 Interpretation and operation of ActDivision 2 Definitions

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investigation warrant means:

- (a) a warrant issued by an issuing officer under section 156; or
- (b) a warrant signed by an issuing officer under section 156A.

issuing officer means a magistrate.

jurisdiction means the following:

- (a) the Commonwealth;
- (b) a State.

licence holder means the holder of a GMO licence.

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

mitochondrial donation licence has the same meaning as in the *Research Involving Human Embryos Act 2002*, and includes a purported mitochondrial donation licence (within the meaning of that Act).

mitochondrial donation technique has the same meaning as in the *Research Involving Human Embryos Act 2002*.

monitoring powers has the meaning given by sections 146A, 146B, 146C, 146CA and 146D.

monitoring warrant means a warrant issued under section 149.

non-notifiable dealing has the meaning given by subsection 75E(1).

notifiable dealing has the meaning given by subsection 74(1).

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

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

- (a) a Minister;
- (b) a person who holds:
 - (i) an office established by or under an Act; or
 - (ii) an appointment made under an Act; or

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- (iii) an appointment made by the Governor-General or a Minister but not under an Act:
- (c) a person who is a member or officer of a Commonwealth authority;
- (d) a person who is in the service or employment of the Commonwealth or of a Commonwealth authority, or is employed or engaged under an Act.

organisation means any of the following:

- (a) a Commonwealth agency;
- (b) a Commonwealth authority;
- (c) a State agency;
- (d) a body corporate;
- (e) an individual.

organism means any biological entity that is:

- (a) viable; or
- (b) capable of reproduction; or
- (c) capable of transferring genetic material.

permit dealing has the meaning given by subsection 72AB(1).

permit holder means the holder of a GMO permit.

person assisting an authorised inspector has the meaning given by subsection 143(1).

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

person covered by a GMO permit means a person authorised by a GMO permit to deal with a GMO.

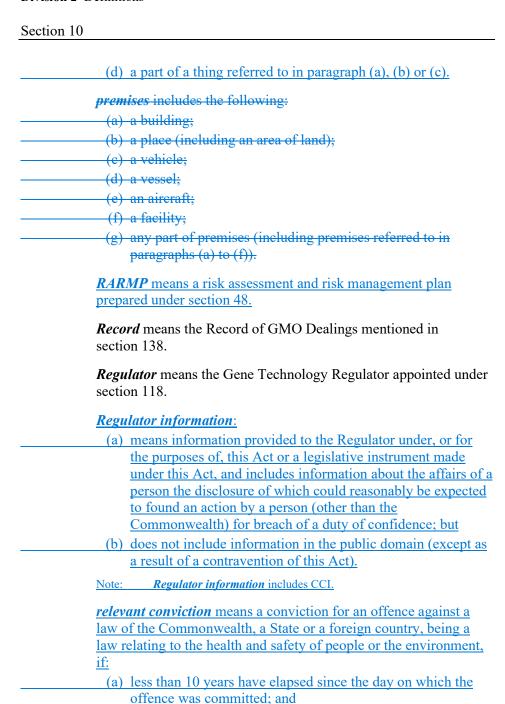
premises includes the following:

- (a) a structure, vehicle, vessel or aircraft;
- (b) a place (including an area of land and whether or not enclosed or built on);
- (c) a facility;

Gene Technology Act 2000

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Part 2 Interpretation and operation of ActDivision 2 Definitions



Interpretation and operation of Act Part 2
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Section 10

- (b) the offence was punishable on conviction:
 - (i) for a natural person—by a fine of \$5,000 or more, or by a term of imprisonment of one year or more; or
 - (ii) for a body corporate—by a fine of \$25,000 or more.

relevant data has the meaning given by subsection 146B(4).

reviewable decision has the meaning given by section 179.

rules means the rules made under section 193A.

State includes the Australian Capital Territory and the Northern Territory.

State agency means the following:

- (a) the Crown in right of a State;
- (b) a Minister of a State;
- (c) a State Government Department;
- (d) an instrumentality of a State, including a body corporate established for a public purpose by or under a law of a State;
- (e) a company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together:
 - (i) the Crown in right of a State;
 - (ii) a person or body covered by paragraph (b) or (d);
 - (iii) a person or body covered by either of the above subparagraphs.

subject to an infringement notice has the meaning given by section 164.

subject to a publication requirement, for Regulator information, has the meaning given by section 184.

subject to investigation has the meaning given by section 151A.

subject to monitoring has the meaning given by subsections 145A(1) and (2).

Part 2 Interpretation and operation of ActDivision 2 Definitions

Section 11

thing includes, but is not limited to, the following:
(a) equipment;
(b) a substance or material;
(c) an animal, plant or other biological entity (including a
<u>GMO);</u>
(d) any part or product of an animal, plant or other biological
entity (including a GMO);
(e) any thing that is, or is intended to be, used in relation to
dealing with a GMO;
(f) a structure, facility, vehicle, vessel or aircraft;
(g) information in a form capable of being communicated,
analysed or processed (whether by an individual or by
computer or other automated means).

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

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

11 Meaning of intentional release of a GMO into the environment

For the purposes of this Act, a dealing with a GMO involves the *intentional release of the GMO into the environment* if the GMO is intentionally released into the open environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment.

12 Meaning of corresponding State law

- (1) For the purposes of this Act, *corresponding State law* means a State law that is declared by the Minister, by <u>notifiable</u> <u>instrumentnotice in the *Gazette*</u>, to correspond to this Act and the regulations, including such a law as amended from time to time.
- (2) The Minister may revoke a <u>notifiable instrument madeGazette</u> notice under subsection (1) in relation to a State law only if:

Interpretation and operation of Act Part 2
Definitions Division 2

Section 12A

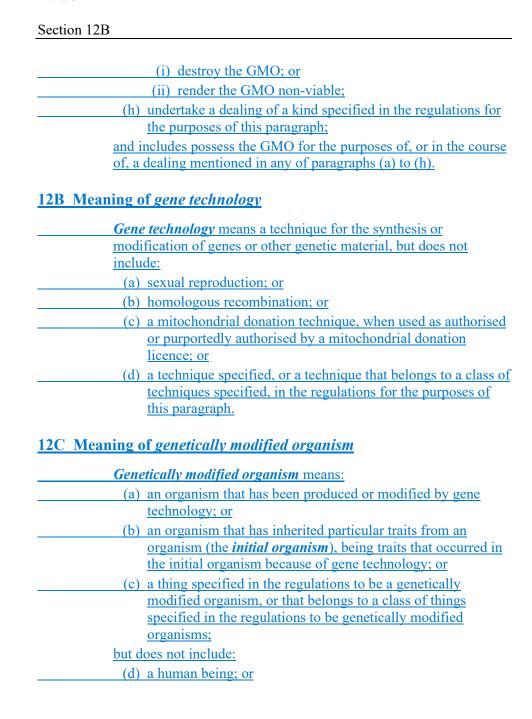
- (a) the Minister is requested by the State concerned to revoke the instrumentnotice; or
- (b) the State law has been amended otherwise than as agreed by a majority of the members of the Ministerial Council (being a majority that includes the Commonwealth) under the Gene Technology Agreement; or
- (c) amendments of the State law have been agreed by a majority of the members of the Ministerial Council (being a majority that includes the Commonwealth) under the Gene Technology Agreement, and the State law has not been amended in accordance with that agreement within a reasonable period after the agreement.

12A Meaning of deal with

(1) Deal with , in relation to a GMO, means any of the following:
(a) produce the GMO, which includes:
(i) make the GMO; or
(ii) develop the GMO; or
(iii) manufacture the GMO; or
(iv) breed the GMO; or
(v) propagate the GMO; or
(vi) grow the GMO; or
(vii) raise the GMO; or
(viii) culture the GMO;
(b) store the GMO;
(c) use the GMO, which includes:
(i) conduct experiments with the GMO; or
(ii) use the GMO in the course of manufacture of a thing
that is not the GMO; or
(iii) release the GMO into the environment;
(d) supply the GMO;
(e) import the GMO;
(f) transport the GMO;
(g) dispose of the GMO, which includes:

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Part 2 Interpretation and operation of ActDivision 2 Definitions



Interpretation and operation of Act Part 2
Definitions Division 2

Section 12C

(e) a thing specified in the regulations not to be a genetically modified organism, or that belongs to a class of things specified in the regulations not to be genetically modified organisms.

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Part 2 Interpretation and operation of ActDivision 3 Operation of Act

Section 13

Division 3—Operation of Act

13 Operation of Act

- (1) This Act applies as follows:
 - (a) to things done, or omitted to be done, by constitutional corporations;
 - (b) to things done, or omitted to be done, in the course of constitutional trade or commerce;
 - (c) to things done, or omitted to be done, by a person that may cause the spread of diseases or pests;
 - (d) for purposes relating to the collection, compilation, analysis and dissemination of statistics;
 - (e) to the Commonwealth and Commonwealth authorities;
 - (f) to things authorised by the legislative power of the Commonwealth under paragraph 51(xxxix) of the Constitution, so far as it relates to the matters mentioned in paragraphs (a) to (e) of this subsection.

(2) In this section:

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

constitutional trade or commerce means trade or commerce:

- (a) between Australia and places outside Australia; or
- (b) among the States; or
- (c) by way of the supply of services to the Commonwealth or to a Commonwealth authority.

14 Wind-back of reach of Act

- (1) This section applies to a State (the *notifying State*) at a particular time if:
 - (a) a corresponding State law is in force in the notifying State at that time; and

Interpretation and operation of Act Part 2
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Section 15

- (b) a wind-back notice in relation to that State is in force at that time.
- (2) This Act applies as a law of the Commonwealth in the notifying State with the following modifications:
 - (a) this Act applies as if paragraph 13(1)(c) (which deals with the spread of pests and diseases) had not been enacted;
 - (b) this Act does not apply to a dealing with a GMO undertaken:
 - (i) by a higher education institution or a State agency; or
 - (ii) by a person authorised to undertake the dealing by a <u>GMO licence or GMO permitlicence</u> held under the corresponding State law by a higher education institution or a State agency.
- (3) In this section:

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

15 Relationship to other Commonwealth laws

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

15A Minister and Regulator not required to consider certain risks

- (1) This section applies if the Minister or the Regulator is required under this Act to take into account, be satisfied or give advice in relation to, risks posed by dealings with a GMO.
- (2) The Minister or Regulator is not required to consider a particular risk if:
 - (a) the risk is dealt with under any of the following Acts, or a legislative instrument made under any of the following Acts:

Gene Technology Act 2000

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Part 2 Interpretation and operation of ActDivision 3 Operation of Act

Section 15A



dealings is to suppress or eradicate the weed, pest or pathogen.

Interpretation and operation of Act Part 2 Provisions to facilitate a nationally consistent scheme Division 4

Section 16

Division 4—Provisions to facilitate a nationally consistent scheme

Subdivision A—General provisions

16 State laws may operate concurrently

- (1) This Act is not intended to exclude the operation of any State law, to the extent that the State law is capable of operating concurrently with this Act, other than a State law prescribed by the regulations for the purposes of this section.
- (2) The Governor-General may prescribe a State law under subsection (1) only if:
 - (a) there is no corresponding State law in effect in relation to that State; and
 - (b) either:
 - (i) the State law relates specifically to dealings with GMOs; or
 - (ii) for the purposes of a decision under the State law as to whether or not a licence, authority or approval (however described) is granted under the State law, the State law distinguishes between dealings with GMOs and dealings with other things.

17 Conferral of functions on Commonwealth officers and bodies

- (1) A corresponding State law may confer functions, powers and duties on the following:
 - (a) the Regulator or another officer of the Commonwealth;
 - (b) a Commonwealth authority;
 - (c) the <u>Gene Technology Ethics and Community Consultative</u>
 <u>Committee Ethics and Community Committee</u>;
 - (e) the Gene Technology Technical Advisory Committee.

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Part 2 Interpretation and operation of ActDivision 4 Provisions to facilitate a nationally consistent scheme

Section 18

- (2) If a function, power or duty is conferred on a person or body under subsection (1), the person or body may perform the function or duty or exercise the power, as the case requires.
- (3) If a corresponding State law is expressed to confer on the Regulator the power to determine that dealings be included on the GMO Register, the Regulator may include the dealings on the GMO Register in accordance with the corresponding State law.
- (4) If a corresponding State law is expressed to confer on the Regulator the power to vary the GMO Register, the Regulator may vary the GMO Register in accordance with the corresponding State law.
- (5) If a corresponding State law is expressed to confer on the Regulator the power to enter information on the Record of GMO Dealings, the Regulator may enter the information on the Record in accordance with the corresponding State law.
- (6) The Regulator may:
 - (a) make any notations in the GMO Register that the Regulator considers necessary to identify entries that relate to dealings included on the Register as mentioned in subsection (3) or (4); and
 - (b) make any notations in the Record of GMO Dealings that the Regulator considers necessary to identify entries that relate to information entered on the Record as mentioned in subsection (5).

18 No doubling-up of liabilities

- (1) If:
 - (a) an act or omission is an offence against this Act and is also an offence against a corresponding State law; and
 - (b) the offender has been punished for the offence, or has paid an infringement notice, in respect of the act or omission under the corresponding State law;

Interpretation and operation of Act Part 2 Provisions to facilitate a nationally consistent scheme Division 4

Section 19

the offender is not liable to be punished for the offence under this Act.

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

19 Review of certain decisions

- (1) Application may be made to the Administrative Appeals Tribunal for review of a reviewable State decision.
- (2) A decision made by the Regulator in the performance of a function or the exercise of a power conferred by a corresponding State law is a *reviewable State decision* for the purposes of this section if:
 - (a) the law under which the decision was made provides for review by the Administrative Appeals Tribunal; and
 - (b) the decision is declared by the regulations to be a reviewable State decision for the purposes of this section.
- (3) For the purposes of this section, the *Administrative Appeals Tribunal Act 1975* has effect as if a corresponding State law were an enactment.

20 Things done for multiple purposes

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

Part 2 Interpretation and operation of ActDivision 4 Provisions to facilitate a nationally consistent scheme

Section 21

Subdivision B—Policy principles and policy guidelines

Subdivision B Policy principles, policy guidelines and codes of practice

21 Ministerial Council may issue policy principles

- (1) The Ministerial Council may, by legislative instrument, issue policy principles in relation to the following:
 - (a) ethical issues relating to dealings with GMOs;
 - (aa) recognising areas, if any, designated under State law for the purpose of preserving the identity of one or both of the following:
 - (i) GM crops;
 - (ii) non-GM crops;

for marketing purposes;

- (b) matters relating to dealings with GMOs prescribed by the regulations for the purposes of this paragraph.
- Note 1: The Regulator must not issue a GMO licence or a GMO permit if the Regulator is satisfied that to do so would be inconsistent with a policy principle (see sections 57 and 72AD).
- Note 1: Section 57 provides that the Regulator must not issue a licence if to do so would be inconsistent with a policy principle.
- Note 2: Subsection 33(3) of the *Acts Interpretation Act 1901* confers power to revoke or amend an instrument issued under an Act.
- (2) Before issuing a policy principle, the Ministerial Council must be satisfied that the policy principle was developed in accordance with section 22.
- (3) Regulations for the purposes of paragraph (1)(b) may relate to matters other than the health and safety of people or the environment, but must not derogate from the health and safety of people or the environment.
- (4) Section 42 (disallowance) of the *Legislation Act 2003* does not apply to a policy principle issued under subsection (1).

Interpretation and operation of Act Part 2 Provisions to facilitate a nationally consistent scheme Division 4

Section 22

22 Consultation on policy principles

- (1) Policy principles are to be developed in consultation with the following:
 - (a) the Gene Technology Technical Advisory Committee;
 - (b) the Regulator;
 - (c) the Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee;
 - (e) such Commonwealth and State agencies and such regulatory agencies as the Ministerial Council considers appropriate;
 - (f) such industry groups as the Ministerial Council considers appropriate;
 - (g) such environmental, consumer and other groups as the Ministerial Council considers appropriate.
- (2) Consultation under subsection (1) must be in accordance with guidelines (if any) issued by the Ministerial Council for the purposes of this section.

23 Ministerial Council may issue policy guidelines

- (1) The Ministerial Council may issue policy guidelines in relation to matters relevant to the functions of the Regulator.
 - Note 1: Section 56 requires the Regulator to have regard to policy guidelines when deciding an application for a GMO licence. Section 30 provides that the Regulator is not subject to direction in relation to individual decisions.
 - Note 2: Subsection 33(3) of the *Acts Interpretation Act 1901* confers power to revoke or amend an instrument issued under an Act.
- (2) A policy guideline is not a legislative instrument.

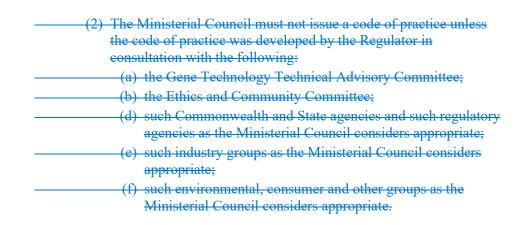
24 Ministerial Council may issue codes of practice

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

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

Part 2 Interpretation and operation of ActDivision 4 Provisions to facilitate a nationally consistent scheme

Section 24



Part 3—The Gene Technology Regulator

25 Simplified outline

The following is a simplified outline of this Part:

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

26 The Gene Technology Regulator

There is to be a Gene Technology Regulator.

27 Functions of the Regulator

The Regulator has the following functions:

- (a) to perform functions in relation to GMO licences as set out in Part 5;
- (aa) to perform functions in relation to GMO permits as set out in Part 5AAA;
- (b) to develop draft policy principles and policy guidelines, as requested by the Ministerial Council;
- (c) to make rules under section 193A;
- (d) to provide technical and procedural guidance in relation to GMOs;
- (da) to exercise monitoring, compliance and enforcement powers under this Act;
- (db) to provide information and advice to the Minister about the operation of this Act or a corresponding State law;
 - (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;

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Section 27A

- (f) to provide information and advice to the public about the regulation of GMOs;
- (g) to provide advice to the Ministerial Council about:
 - (i) the operations of the Regulator and the Gene Technology Technical Advisory Committee; and
 - (ii) the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation;
- (h) to undertake or commission research in relation to risk assessment and the biosafety of GMOs;
- (i) to promote the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies;
- (j) to monitor international practice in relation to the regulation of GMOs;
- (k) to maintain links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia;
- (ka) to promote an internationally consistent approach to GMO regulation, including through the harmonisation, where appropriate, of regulatory practices in relation to GMOs;
 - (l) such other functions as are conferred on the Regulator by this Act, the regulations or any other law.

27A Rules for transport, storage and disposal of GMOs

The rules may specify technical and procedural requirements relating to the transportation, storage and disposal of GMOs.

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.

The Gene Technology Regulator Part 3

Section 29

29 Delegation

- (1) <u>Subject to this section, the Regulator The Regulator</u> may, by instrument in writing, delegate any of the Regulator's powers or functions, other than the powers or functions under section 181 (internal review) or 193A (rules), to any of the following:
 - (a) an employee of the Department;
 - (b) an employee of another Department or of a Commonwealth authority, if the functions of the other Department or Commonwealth authority relate, whether directly or indirectly, to GMOs or GM products;
 - (c) an officer or employee of a State agency, if the functions of the State agency relate, whether directly or indirectly, to GMOs or GM products.
- (1A) The Regulator may delegate the following powers or functions only to an SES employee or acting SES employee of the Department or an authorised inspector:
 - (a) section 164D (withdrawal of an infringement notice);
 - (b) section 165 (acceptance of undertakings);
 - (c) section 165A (enforcement of undertakings);
 - (1B) The Regulator may delegate the following powers or functions only to an SES employee or acting SES employee of the Department:
 - (a) section 166 (grant of injunctions);
 - (b) section 167 (Regulator may give directions).
 - (2) In exercising powers or functions under a delegation, the delegate must comply with any directions of the Regulator.

Gene Technology Act 2000

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30 Independence of the Regulator

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

- (a) whether a GMO licence <u>or GMO permit</u> is issued or refused in relation to a particular application; or
- (b) the conditions to which a particular GMO licence or GMO permit is subject.

Offences and civil penalty provisions **Part 4** Outline and operation of this Part **Division 1**

Section 31

Part 4—Offences and civil penalty provisions

Division 1—Outline and operation of this Part

31 Simplified outline

The following is a simplified outline of this Part:

This Part deals with offences and civil penalty provisions.

A dealing with a GMO by a person is prohibited unless the dealing is an authorised GMO dealing, which is a dealing that:

- (a) is authorised by a GMO licence or GMO permit; or
- (b) is specified in an emergency dealing determination; or
- (c) is a notifiable dealing and the authorisation requirements
 (if any) have been complied with; or
- (d) is a non-notifiable dealing; or
- (e) is included on the GMO Register.

A dealing with a GMO is also an authorised GMO dealing if done by a person exercising powers or performing functions conferred on them under this Act or the regulations, or by a person providing assistance to the Regulator at the Regulator's request.

Certain persons must comply with the conditions to which a GMO licence, a GMO permit, an emergency dealing determination, a notifiable dealing, a dealing on the GMO Register, a certification of a facility, and an accreditation of an organisation are subject.

A person is prohibited from interfering with an authorised GMO dealing and from providing false or misleading information to the Regulator under this Act.

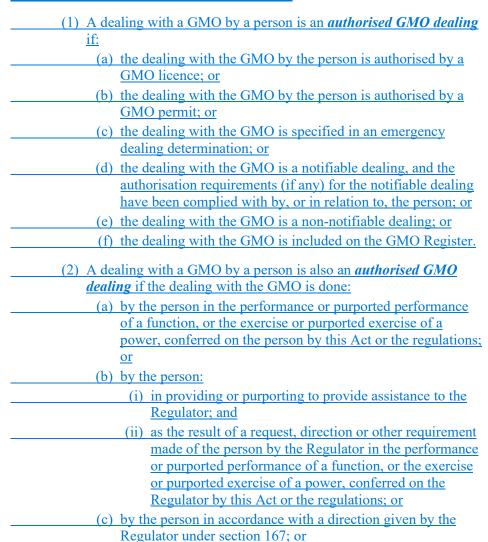
Heavier penalties are imposed for an offence or contravention of a civil penalty provision where the offence or contravention causes,

Part 4 Offences and civil penalty provisionsDivision 1 Outline and operation of this Part

Section 31A

or is likely to cause, significant damage to the health and safety of people or to the environment.

31A Meaning of authorised GMO dealing



Offences and civil penalty provisions **Part 4** Outline and operation of this Part **Division 1**

Section 31A

(d) by the person in accordance with a requirement made by an authorised inspector under paragraph 161A(2)(d).

Part 4 Offences and civil penalty provisionsDivision 2 Dealings with GMOs must be authorised

Section 32

Division 2—Dealings with GMOs must be authorised

32 Dealings with GMOs must be authorised—offence	
A person commits an offence if:	
(a) the person deals with a GMO; and	
(b) the person knows that the GMO is a GMO; and	
(c) the dealing with the GMO by the person is not an authori	sed
GMO dealing.	<u>/Cu</u>
Penalty:	
(a) in the case of an aggravated offence—imprisonment for	
10 years or 4,000 penalty units;	
(b) in any other case—imprisonment for 5 years or 1,000 per	alty
<u>units.</u>	
32A Dealings with GMOs must be authorised—civil penalty	
<u>provision</u>	
A person is liable to a civil penalty if:	
(a) the person deals with a GMO; and	
(b) the dealing with the GMO by the person is not an authori	sed
GMO dealing.	
Civil penalty:	
(a) in the case of an aggravated contravention—1,000 penalt	
	<u> </u>
units;	<u>/</u>

Offences and civil penalty provisions **Part 4**Breach of conditions **Division 3**

Section 33

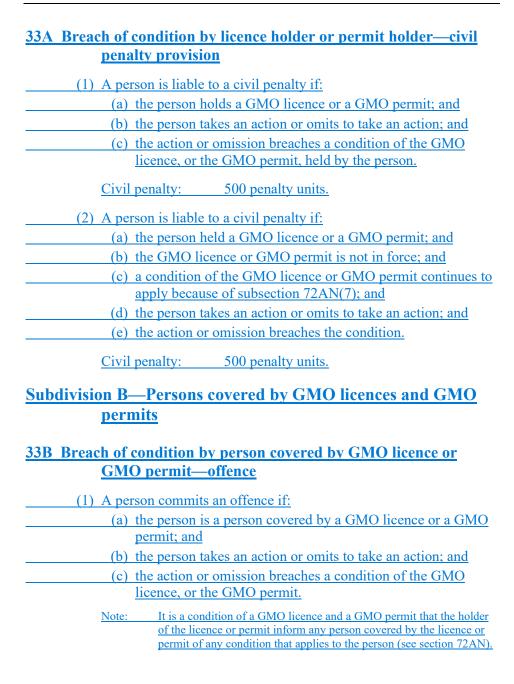
Division 3—Breach of conditions

Subdivision A—Licence holders and permit holders

Subdivision A—Licence holders and permit holders		
33 Breach of condition by licence holder or permit holder—offence		
(1) A person commits an offence if:		
(a) the person holds a GMO licence or a GMO permit; and		
(b) the person takes an action or omits to take an action; and		
(c) the action or omission breaches a condition of the GMO		
licence, or the GMO permit, held by the person.		
Penalty:		
(a) in the case of an aggravated offence—imprisonment for 5		
years or 1,000 penalty units;		
(b) in any other case—imprisonment for 2 years or 500 penalty		
<u>units.</u>		
(2) A person commits an offence if:		
(a) the person held a GMO licence or a GMO permit; and		
(b) the GMO licence or GMO permit is not in force; and		
(c) a condition of the GMO licence or GMO permit continues to		
apply because of subsection 72AN(7); and		
(d) the person takes an action or omits to take an action; and		
(e) the action or omission breaches the condition.		
Penalty: Imprisonment for 2 years or 500 penalty units.		
(3) The maximum penalty for each day that an offence under		
subsection (1) or (2) continues is 10% of the maximum penalty that		
can be imposed in respect of that offence.		
Note: If, for example, a condition of a GMO licence or a GMO permit		
requires an act or thing to be done within a particular period or before		
a particular time, subsections (1) and (2) are continuing offences under section 4K of the <i>Crimes Act 1914</i> .		

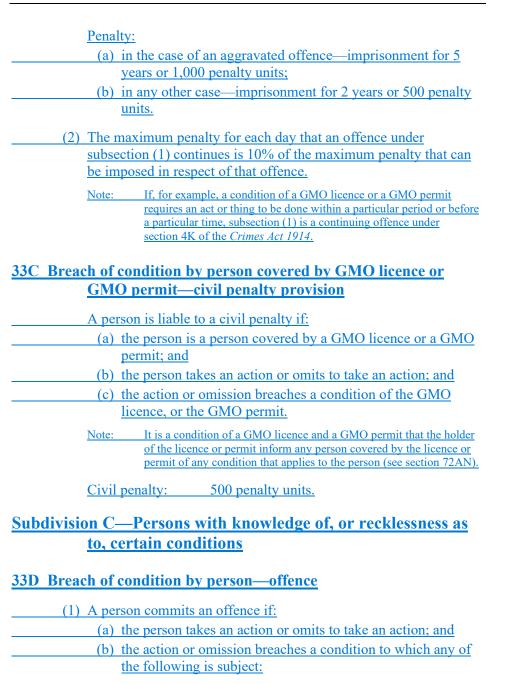
Part 4 Offences and civil penalty provisionsDivision 3 Breach of conditions

Section 33A

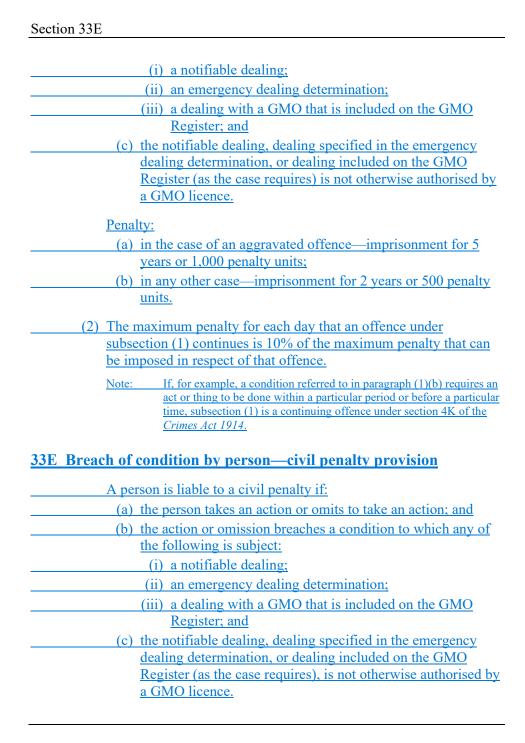


Offences and civil penalty provisions **Part 4**Breach of conditions **Division 3**

Section 33C



Part 4 Offences and civil penalty provisionsDivision 3 Breach of conditions



Offences and civil penalty provisions **Part 4**Breach of conditions **Division 3**

Section 33F

Civil penalty: 500 penalty units. **Subdivision D—Certification and accreditation holders** 33F Breach of condition by holder of certification or accreditation offences (1) A person commits an offence if: (a) the person holds a certification of a facility; and (b) the person takes an action or omits to take an action; and (c) the action or omission breaches a condition of the certification held by the person. Penalty: (a) in the case of an aggravated offence—imprisonment for 5 years or 1,000 penalty units; (b) in any other case—imprisonment for 2 years or 500 penalty units. (2) A person commits an offence if: (a) the person holds an accreditation of an organisation; and (b) the person takes an action or omits to take an action; and (c) the action or omission breaches a condition of the accreditation held by the person. Penalty: Imprisonment for 2 years or 500 penalty units. (3) The maximum penalty for each day that an offence under subsection (1) or (2) continues is 10% of the maximum penalty that can be imposed in respect of that offence. Note: If, for example, a condition of a certification of a facility or an accreditation of an organisation requires an act or thing to be done within a particular period or before a particular time, subsections (1) and (2) are continuing offences under section 4K of the Crimes Act

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1914.

Part 4 Offences and civil penalty provisionsDivision 3 Breach of conditions

Section 33G

33G Breach of condition by holder of certification or accreditation—civil penalty provision

A person is liable to a civil penalty provision if:

- (a) the person holds a certification of a facility or an accreditation of an organisation; and
- (b) the person takes an action or omits to take an action; and
- (c) the action or omission breaches a condition of the certification, or the accreditation, held by the person.

Civil penalty: 500 penalty units.

Offences and civil penalty provisions Part 4 Other offences and civil penalties Division 4

Section 34

Division 4—Other offences and civil penalties

	dealings with GMOs—offence
A person co	ommits an offence if:
(a) the pe	erson engages in conduct; and
-	gaging in the conduct, the person intends to prevent or
hinder	r authorised GMO dealings that are being undertaken at
a pren	nises; and
(c) either	of the following applies:
(i) t	the conduct results in damage to, destruction of, or
<u>i</u>	nterference with, the premises;
(ii) t	the conduct involves damaging, destroying, or
<u>i</u>	nterfering with a thing at, or removing a thing from, the
I	premises; and
	wner or occupier of the premises, or the owner of the
<u>thing</u>	(as the case requires), has not consented to the conduct.
Penalty: In	nprisonment for 2 years or 500 penalty units.
1 Charty. In	iprisonment for 2 years of 500 penalty units.
34A Interference wit	th dealings with GMOs—civil penalty provision
*	liable to a civil penalty if:
-	erson engages in conduct; and
	onduct occurs at premises where authorised GMO
	ngs are being undertaken; and
	of the following applies:
	the conduct results in damage to, destruction of, or
i	
	nterference with, the premises;
(ii) t	interference with, the premises; the conduct involves damaging, destroying, or
(ii) t <u>i</u>	the conduct involves damaging, destroying, or interfering with a thing at, or removing a thing from, the
(ii) t <u>i</u> I	the conduct involves damaging, destroying, or interfering with a thing at, or removing a thing from, the premises; and
(ii) t i (d) the ov	interference with, the premises; the conduct involves damaging, destroying, or interfering with a thing at, or removing a thing from, the

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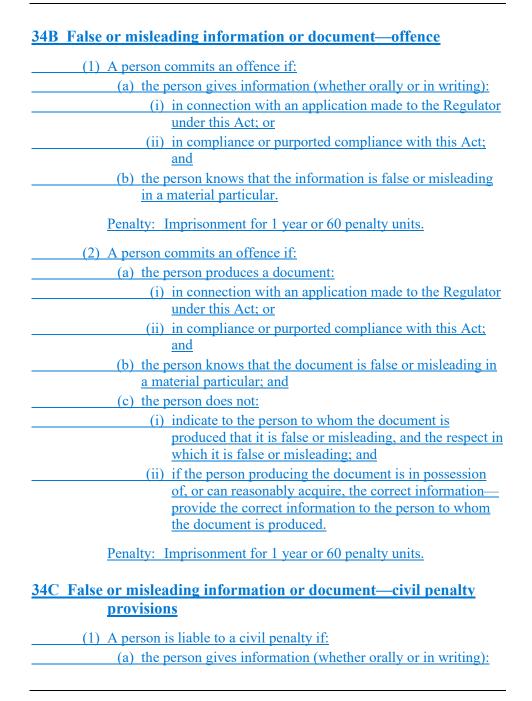
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500 penalty units.

Civil penalty:

Part 4 Offences and civil penalty provisionsDivision 4 Other offences and civil penalties

Section 34B



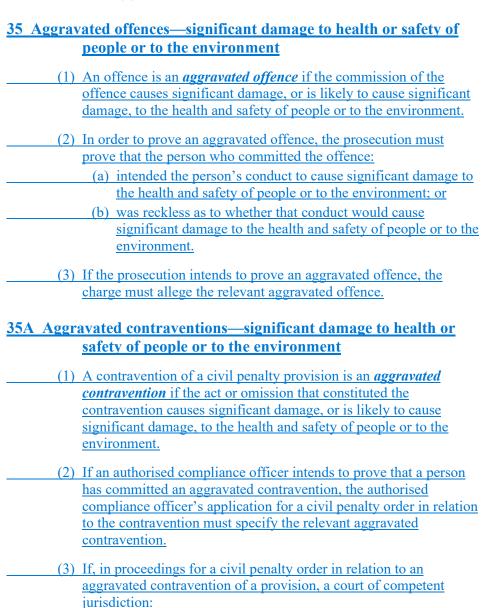
Offences and civil penalty provisions Part 4 Other offences and civil penalties Division 4

Section 34C (i) in connection with an application made to the Regulator under this Act; or (ii) in compliance or purported compliance with this Act; and (b) the information is false or misleading in a material particular. 60 penalty units. Civil penalty: (2) A person is liable to a civil penalty if: (a) the person produces a document: (i) in connection with an application made to the Regulator under this Act; or (ii) in compliance or purported compliance with this Act; and (b) the document is false or misleading in a material particular; and (c) the person does not: (i) indicate to the person to whom the document is produced that it is false or misleading, and the respect in which it is false or misleading; and (ii) if the person producing the document is in possession of, or can reasonably acquire, the correct information provide the correct information to the person to whom the document is produced. 60 penalty units. Civil penalty:

Part 4 Offences and civil penalty provisionsDivision 5 Aggravated offences and contraventions

Section 35





Offences and civil penalty provisions **Part 4** Aggravated offences and contraventions **Division 5**

Section 35A

- (a) is not satisfied that the person has committed an aggravated contravention of that provision; and
- (b) is satisfied, on the balance of probabilities, that the person has contravened that provision;

the court may make a civil penalty order against the person not for the aggravated contravention but for the contravention of that provision.

Part 4 Regulation of dealings with GMOsDivision 1 Simplified outline

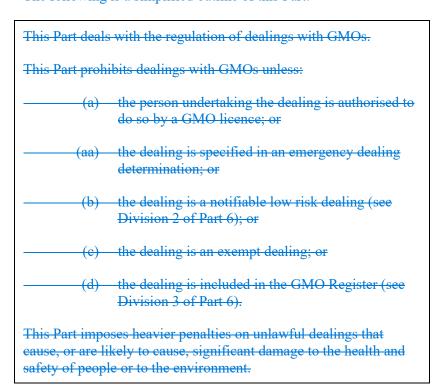
Section 31

Part 4 Regulation of dealings with GMOs

Division 1—Simplified outline

31 Simplified outline

The following is a simplified outline of this Part:



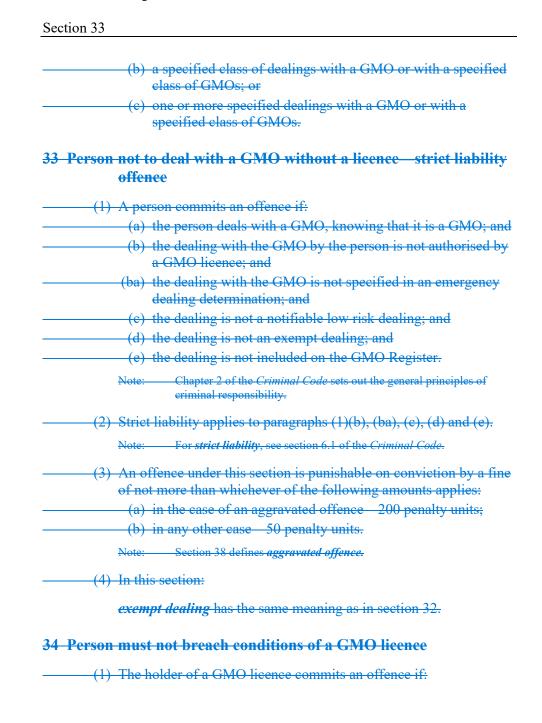
Regulation of dealings with GMOs Part 4
Dealings with GMOs must be licensed Division 2

Section 32

Division 2—Dealings with GMOs must be licensed

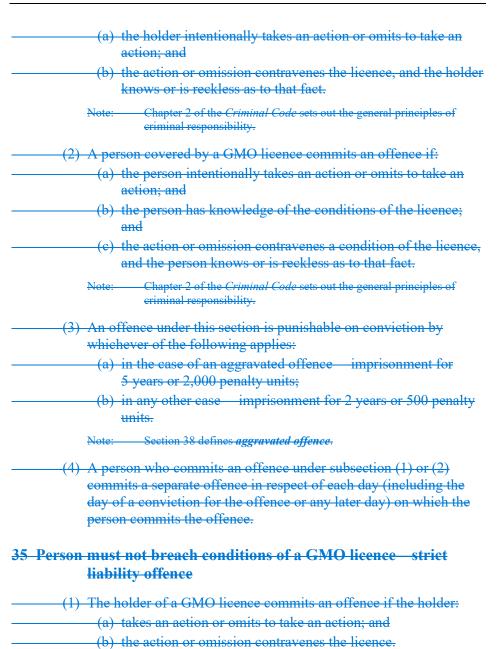
32 Person not to deal with a GMO without a licence (1) A person commits an offence if: (a) the person deals with a GMO, knowing that it is a GMO; and (b) the dealing with the GMO by the person is not authorised by a GMO licence, and the person knows or is reckless as to that fact; and (c) the dealing with the GMO is not specified in an emergency dealing determination, and the person knows or is reckless as to that fact; and (d) the dealing is not a notifiable low risk dealing, and the person knows or is reckless as to that fact; and (e) the dealing is not an exempt dealing, and the person knows or is reckless as to that fact; and (f) the dealing is not included on the GMO Register, and the person knows or is reckless as to that fact. Chapter 2 of the Criminal Code sets out the general principles of criminal responsibility. (2) An offence under subsection (1) is punishable on conviction by whichever of the following applies: (a) in the case of an aggravated offence imprisonment for 5 years or 2,000 penalty units; (b) in any other case imprisonment for 2 years or 500 penalty Section 38 defines aggravated offence. Note: (3) In this section: exempt dealing means a dealing specified by the regulations to be an exempt dealing. (4) Regulations under subsection (3) may be expressed to exempt: (a) all dealings with a GMO or with a specified class of GMOs;

Part 4 Regulation of dealings with GMOsDivision 2 Dealings with GMOs must be licensed



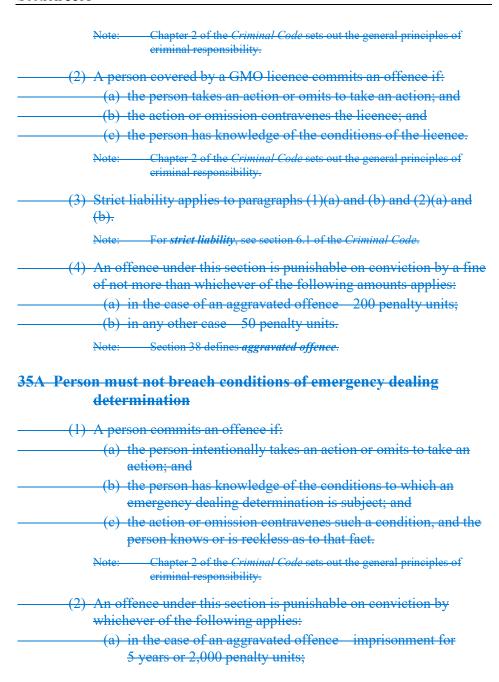
Regulation of dealings with GMOs Part 4
Dealings with GMOs must be licensed **Division 2**

Section 35



Part 4 Regulation of dealings with GMOsDivision 2 Dealings with GMOs must be licensed

Section 35A



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Regulation of dealings with GMOs Part 4
Dealings with GMOs must be licensed Division 2

Section 35B (b) in any other case imprisonment for 2 years or 500 penalty units. Section 38 defines aggravated offence. 35B Person must not breach conditions of emergency dealing determination strict liability offence (1) A person commits an offence if: (a) the person takes an action or omits to take an action; and (b) the person has knowledge of the conditions to which an emergency dealing determination is subject; and (c) the action or omission by the person contravenes such a condition. Chapter 2 of the Criminal Code sets out the general principles of Note: criminal responsibility. (2) Strict liability applies to paragraphs (1)(a) and (c). Note: For strict liability, see section 6.1 of the Criminal Code. (3) An offence under this section is punishable on conviction by a fine of not more than whichever of the following amounts applies: (a) in the case of an aggravated offence 200 penalty units; (b) in any other case 50 penalty units. Section 38 defines aggravated offence. 36 Person must not breach conditions on GMO Register (1) A person commits an offence if the person: (a) deals with a GMO, knowing that it is a GMO; and (b) the dealing is on the GMO Register; and (c) the dealing contravenes a condition relating to the dealing that is specified in the GMO Register. Maximum penalty: 50 penalty units.

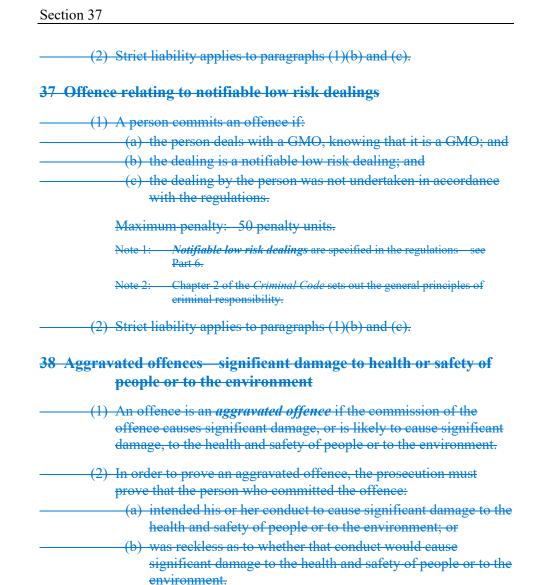
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Chapter 2 of the Criminal Code sets out the general principles of

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criminal responsibility.

Part 4 Regulation of dealings with GMOsDivision 2 Dealings with GMOs must be licensed



GMO licencesLicensing system **Part 5**Simplified outline **Division 1**

Section 39

Part 5—GMO licences Licensing system

Division 1—Simplified outline

39 Simplified outline

The following is a simplified outline of this Part:

This Part provides for a licensing system under which a person may apply to the Regulator for a GMO licence. A GMO licence authorises one or more dealings with one or more GMOs.

In some circumstances, the Regulator must prepare a risk assessment and risk management plan and consult in relation to the plan.

The Regulator must not issue a GMO licence unless satisfied of certain things, including that any risks associated with the proposed dealings will be managed and that the person is a suitable person to hold a GMO licence.

A GMO licence is subject to conditions.

A GMO licence may be suspended, cancelled, varied, transferred to another person or surrendered.

39 Simplified outline

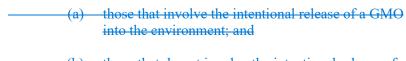
The following is a simplified outline of this Part:

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

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

Part 5 GMO licencesLicensing systemDivision 1 Simplified outline





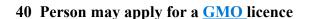
(b) those that do not involve the intentional release of a GMO into the environment.

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

GMO licencesLicensing system Part 5 GMO licenceLicence applications Division 2

Section 40

Division 2—GMO licence Licence applications



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

Note: Division 1A of Part 12 sets out requirements for applications.

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

 (a) such information as is prescribed by the regulations (if any);
 and
 - (b) such information as is specified in writing by the Regulator.
 - (3) The application must specify whether any of the dealings proposed to be authorised by the licence would involve the intentional release of a GMO into the environment.
 - (4) The dealings in respect of which a person may apply for a <u>GMO</u> licence may be:
 - (a) all dealings with a GMO, or with a specified class of GMOs; or
 - (b) a specified class of dealings with a GMO, or with a specified class of GMOs; or
 - (c) one or more specified dealings with a GMO, or with a specified class of GMOs.
- (5) The applicant may apply for a licence authorising such dealings by:
 - (a) a specified person or persons; or
 - (b) a specified class of person; or
 - (c) all persons.
 - (6) The application must be accompanied by the application fee (if any) prescribed by the regulations.

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Section 40A

40A GMO licences Licences relating to inadvertent dealings

- If the Regulator is satisfied that a person has come into possession of a GMO inadvertently the Regulator may, with the agreement of the person, treat the person as having made an inadvertent dealings application.
- (2) To avoid doubt, subsection (1) does not prevent a person from making an application under section 40 in respect of a GMO that has inadvertently come into the person's possession.

Note: Section 47 has the effect that the Regulator may expedite

consideration of an application to deal with a GMO in certain ways if
the GMO has come into a person's possession inadvertently. That
section has effect whether the application is made under section 40, or
is taken to have been made under this section.

Note: Sections 46A and 49 have the effect that the Regulator may expedite

Sections 46A and 49 have the effect that the Regulator may expedite consideration of an application to dispose of a GMO that has come into a person's possession inadvertently. These sections have effect whether the application is made under section 40, or is taken to have been made under this section.

41 Application may be withdrawn

- (1) The applicant may withdraw the application at any time before the licence is issued.
- (2) The application fee is not refundable if the applicant withdraws the application.

42 Regulator may require applicant to give further information

- (1) The Regulator may, by notice in writing, require an applicant for a licence to give the Regulator such further information in relation to the application as the Regulator requires.
 - (2) The notice may specify the period within which the information is to be provided.
- (3) The Regulator may require information to be given under this section at any time before the Regulator decides the application,

GMO licencesLicensing system Part 5 GMO licenceLicence applications Division 2

Section 43

whether before or after the Regulator has begun to consider the application.

43 Regulator must consider applications except in certain circumstances

- (1) The Regulator must consider an application under section 40 for a <u>GMO</u> licence in accordance with this Part and <u>Division 1A of</u> Part 12.
- (2) However, the Regulator is not required to consider the application, or may cease considering the application, if:
 - (a) the application does not contain the information specified by the Regulator or prescribed by the regulations; or
 - (b) the application does not satisfy subsection 40(3); or
 - (c) the application is not accompanied by the application fee (if any) prescribed by the regulations; or
 - (d) the applicant did not provide further information required by the Regulator by notice under section 42 within the period specified in the notice; or
 - (e) the Regulator is satisfied that to issue the <u>GMO</u> licence would be inconsistent with a policy principle in force under section 21; or
 - (f) the Regulator is satisfied (having regard to the matters specified in section 72AM) that the applicant is not a suitable person to hold a GMO licence.
 - (f) the Regulator is satisfied (having regard to the matters specified in section 58) that the applicant is not a suitable person to hold a licence.
- (3) The Regulator must issue the licence, or refuse to issue the licence, within the period (if any) prescribed by the regulations.

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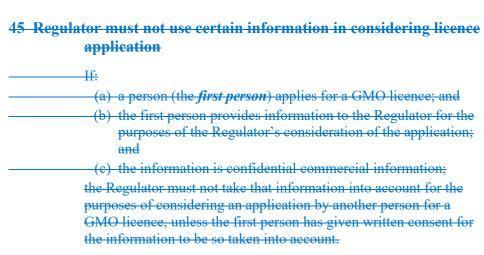
Part 5 GMO licencesLicensing systemDivision 2 GMO licenceLicence applications

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44 Regulator may consult before considering application

44 Regulator may consult with applicant

Before considering an application in accordance with the requirements of this Part and Division 1A of Part 12, the Regulator may consult any person or body the Regulator may consult under section 46the applicant, or another regulatory agency, on any aspect of the application.



GMO licencesLicensing system Part 5 Consideration of GMO licence applications Division 3

Section 46

Division 3—Consideration of GMO licence applications

46 Regulator may consult on application

For the pu	rposes of considering an application for a GMO licence,
	ator may consult one or more of the following about any
aspect of t	he application:
(a) the a	applicant;
(b) a Sta	<u>ate;</u>
(c) the (Gene Technology Technical Advisory Committee;
(d) relev	vant Commonwealth authorities or agencies;
(e) any	other person or body the Regulator considers
appr	opriate.

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Part 5 GMO licencesLicensing systemDivision 4 Risk assessment and risk management plans

Section 47

Division 4—Risk assessment and risk management plans

47 Applications to which this Division applies

This Division applies to an application for a GMO licence, other than an inadvertent dealings application.

48 Preparation of risk assessment and risk management plans

- (1) Before issuing a GMO licence, the Regulator must prepare a risk assessment and risk management plan (the *RARMP*) in relation to the dealings proposed to be authorised by the GMO licence.
- (2) In preparing the RARMP, the Regulator must take into account the <u>following:</u>
 - (a) the risks posed by the dealings to the health and safety of people and to the environment;
 - (b) the means of managing those risks in such a way as to protect the health and safety of people and to protect the environment;
 - (c) any other matter prescribed by the regulations for the purposes of this paragraph.

Note: Despite subsection (2), the Regulator is not required to consider risks posed by the dealings proposed to be authorised by the GMO licence in certain circumstances (see section 15A).

49 Consultation on risk assessment and risk management plans

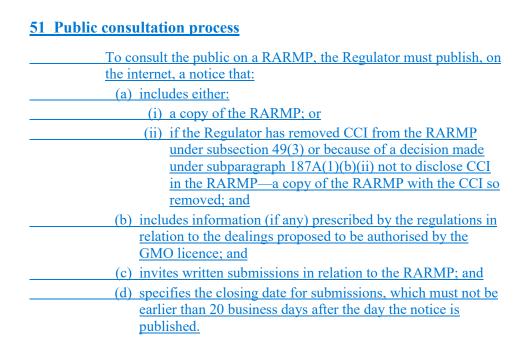
- (1) After a RARMP has been prepared, the Regulator:
 - (a) must consult each person or body (if any) prescribed by the regulations on the RARMP; and
 - (b) must consult the public on the RARMP if the Regulator is satisfied that any dealing to be authorised by the GMO licence would involve:
 - (i) a GMO that is derived from a parent organism that is novel; or

GMO licencesLicensing system Part 5 Risk assessment and risk management plans Division 4

Section 50 (ii) a GMO that displays a novel trait that occurs because of gene technology; and (c) may consult the public on the RARMP if the Regulator considers it to be in the public interest to do so. Note 1: The regulations may prescribe by class: see subsections 33(3A) and (3B) of the Acts Interpretation Act 1901. If the Regulator must, or decides to, publicly consult on a RARMP, Note 2: the information in the RARMP is subject to a publication requirement (see Subdivision A of Division 3 of Part 12). In those circumstances, the Regulator must undertake certain steps before publicly disclosing the information. (2) Despite paragraph (1)(b), the Regulator is not required to consult the public on the RARMP if the Regulator is satisfied that each dealing covered by subparagraph (1)(b)(i) or (ii) will: (a) be conducted in a facility that is certified under Division 2 of Part 7; or (b) involve using the GMO: (i) by administering it into a human for therapeutic purposes; or (ii) to produce therapeutic goods (within the meaning of the Therapeutic Goods Act 1989); or (c) be conducted in accordance with rules made for the purposes of section 27A (rules for transport, storage and disposal of GMOs). (3) The Regulator may remove CCI contained in the RARMP before consultation under subsection (1) if the Regulator considers there is no public interest in publicly disclosing the CCI. 50 Notice to applicant of public consultation (1) Before the Regulator consults the public on a RARMP, the Regulator must give the applicant written notice of the consultation. (2) The notice must be given within 60 business days after the Regulator receives the application for the GMO licence.

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Section 51



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

Section 46

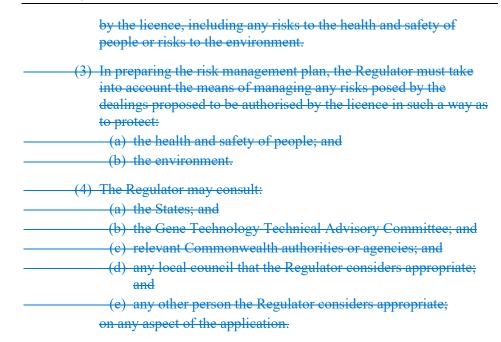
Division 3 Initial consideration of licences for dealings not involving intentional release of a GMO into the environment

46 Applications to which this Division applies This Division applies to an application for a GMO licence if the Regulator is satisfied that none of the dealings proposed to be authorised by the licence would involve the intentional release of a GMO into the environment. 46A Division does not apply to an application relating to inadvertent dealings Despite section 46, this Division does not apply to an application for a GMO licence if the Regulator is satisfied that: (a) the dealings proposed to be authorised by the licence are limited to one or more of the following for purposes relating to disposing of a GMO: (i) conducting experiments with the GMO; (ii) propagating the GMO; (iii) growing, raising or culturing the GMO; (iv) transporting the GMO; (v) any other dealings to be undertaken for the purposes of, or for purposes relating to, disposing of the GMO; and (b) the applicant for the licence came into possession of the GMO inadvertently. 47 What the Regulator must do in relation to application (1) Before issuing the licence, the Regulator must prepare a risk assessment and a risk management plan in relation to the dealings proposed to be authorised by the licence. (2) In preparing the risk assessment, the Regulator must take into account the risks posed by the dealings proposed to be authorised

Part 5 GMO licencesLicensing system

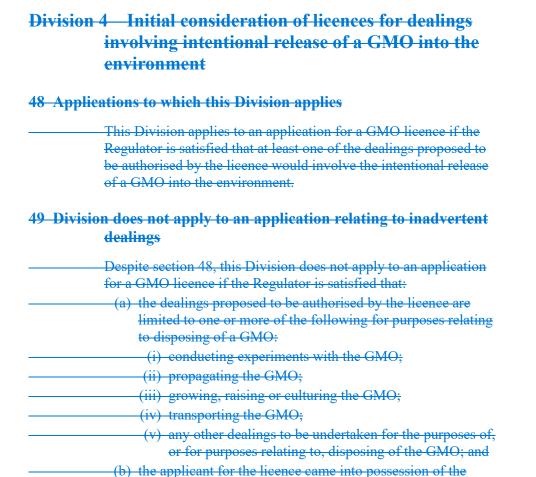
Division 3 Initial consideration of licences for dealings not involving intentional release of a GMO into the environment





GMO licencesLicensing system Part 5
Initial consideration of licences for dealings involving intentional release of a GMO into
the environment Division 4

Section 48



50 Regulator must prepare risk assessment and risk management plan

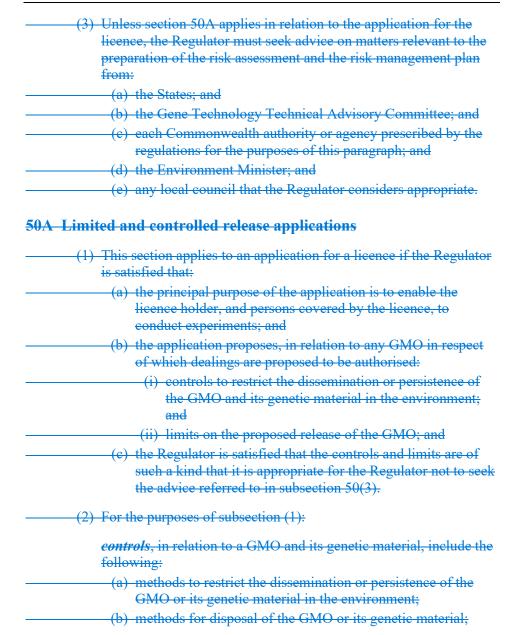
GMO inadvertently.

(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.

Part 5 GMO licencesLicensing system

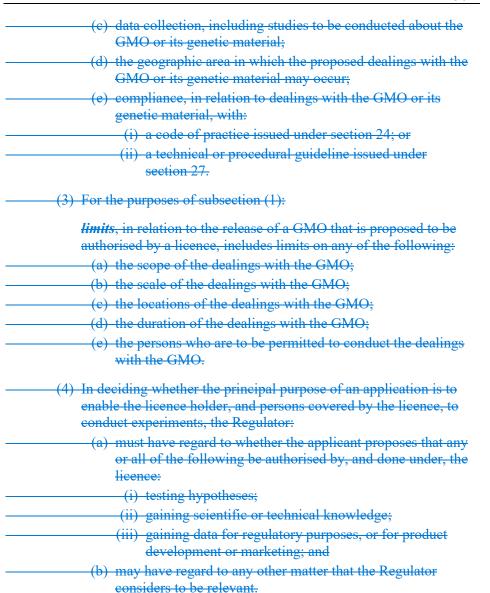
Division 4 Initial consideration of licences for dealings involving intentional release of a GMO into the environment

Section 50A



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

Section 50A



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

Section 51

51 Matters Regulator must take into account in preparing risk assessment and risk management plan
(1) In preparing the risk assessment in relation to the dealings proposed to be authorised by the licence, the Regulator must take into account the following:
(a) the risks posed by those dealings, including any risks to the health and safety of people or risks to the environment, having regard to the matters prescribed by the regulations;
(c) any advice in relation to the risk assessment provided by a State or a local council in response to a request under subsection 50(3);
(d) any advice in relation to the risk assessment provided by the Gene Technology Technical Advisory Committee in response to a request under subsection 50(3);
(e) any advice in relation to the risk assessment provided by a Commonwealth authority or agency in response to a request under subsection 50(3);
(f) any advice in relation to the risk assessment provided by the Environment Minister in response to a request under subsection 50(3);
(g) any other matter prescribed by the regulations for the purposes of this paragraph.
(2) In preparing the risk management plan, the Regulator must take into account the following:
(a) the means of managing any risks posed by those dealings in such a way as to protect:
(i) the health and safety of people; and (ii) the environment;
(c) any advice in relation to the risk management plan provided by a State or a local council in response to a request under subsection 50(3);
(d) any advice in relation to the risk management plan provided by the Gene Technology Technical Advisory Committee in response to a request under subsection 50(3);

GMO licencesLicensing system Part 5
Initial consideration of licences for dealings involving intentional release of a GMO into the environment **Division 4**

Section 52 (e) any advice in relation to the risk management plan provided by a Commonwealth authority or agency in response to a request under subsection 50(3); (f) any advice in relation to the risk management plan provided by the Environment Minister in response to a request under subsection 50(3); (g) any other matter prescribed by the regulations for the purposes of this paragraph. (3) For the avoidance of doubt, in taking into account the means of managing risks as mentioned in paragraph (2)(a), the Regulator: (a) is not limited to considering submissions or advice mentioned in paragraphs (2)(b), (c), (d), (e) and (f); and (b) subject to section 45, may take into account other information, including, but not limited to, relevant independent research. 52 Public notification of risk assessment and risk management plan (1) After taking the steps referred to in sections 50 and 51, the Regulator must publish a notice: (a) in the Gazette; and (b) in one or more newspapers that the Regulator considers appropriate, having regard to the geographic area in which the dealings proposed to be authorised by the licence may occur; and (c) on the Regulator's website. (2) The notice must: (a) state that a risk assessment and a risk management plan have been prepared in respect of dealings proposed to be authorised by the licence; and

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(b) state that a person may request further information about the risk assessment and the risk management plan under

(ba) if the Regulator is satisfied that one or more dealings proposed to be authorised by the licence may pose a

section 54; and

Part 5 GMO licencesLicensing system

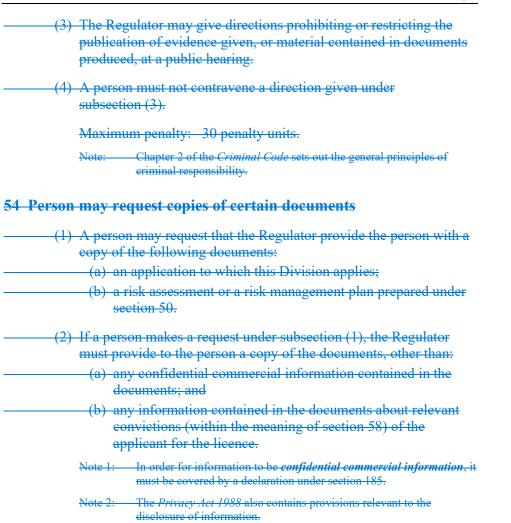
Division 4 Initial consideration of licences for dealings involving intentional release of a GMO into the environment

Section 53 significant risk to the health and safety of people or to the environment state that the Regulator is so satisfied; and 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: (i) if the notice states that the Regulator is satisfied that the dealings proposed to be authorised by the licence may pose a significant risk to the health and safety of people or to the environment 50 days after the date on which the notice was published; or (ii) in any other case 30 days after the date on which the notice was published. (3) The Regulator must also seek advice on the risk assessment and the risk management plan from: (a) the States; and (b) the Gene Technology Technical Advisory Committee; and (c) each Commonwealth authority or agency prescribed by the regulations for the purposes of this paragraph; and (d) the Environment Minister; and (e) any local council that the Regulator considers appropriate. 53 Regulator may take other actions (1) In addition to satisfying the requirements of this Division in relation to an application for a licence to which this Division applies, the Regulator may take any other action the Regulator considers appropriate for the purpose of deciding the application, including holding a public hearing. (2) If the Regulator holds a public hearing, the Regulator may, having regard to the requirements of this Act in relation to confidential commercial information, direct that any part of the hearing be held

in private, and may determine who can attend.

GMO licencesLicensing system Part 5
Initial consideration of licences for dealings involving intentional release of a GMO into the environment **Division 4**

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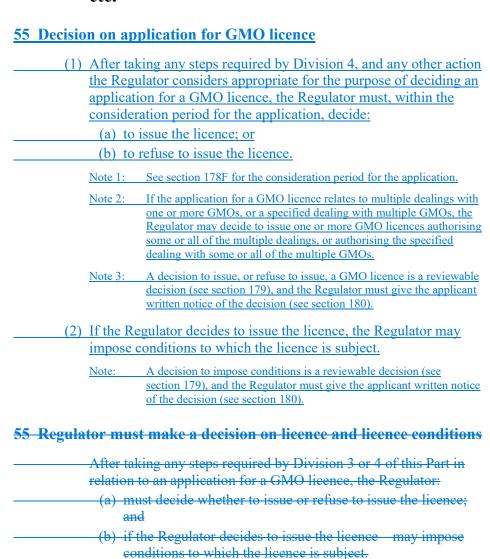


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Section 55

Division 5—Decision on **GMO** licence application licence etc.



GMO licencesLicensing system **Part 5**Decision on GMO licence applicationlicence etc. **Division 5**

Section 56

56 Regulator must not issue <u>GMO licence</u>the licence unless satisfied as to risk management

- (1) The Regulator must not <u>issue a GMO licence</u> 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.

Note: Despite subsection (1), the Regulator is not required to consider risks posed by the dealings in certain circumstances (see section 15A).

- (2) For the purposes of subsection (1), the Regulator must have regard to the following:
 - (a) the RARMP for the application for the GMO licence;
 - (b) any submissions received as a result of consultation under subsection 49(1) in relation to the RARMP for the application for the GMO licence;
 - (a) the risk assessment prepared under section 47 or 50 in relation to the dealings;
 - (b) the risk management plan prepared under section 47 or 50 in relation to the dealings;
 - (c) any submissions received under section 52 in relation to the licence;
 - (d) any policy guidelines in force under section 23 that relate to:
 - (i) risks that may be posed by the dealings proposed to be authorised by the licence; or
 - (ii) ways of managing such risks so as to protect the health and safety of people or to protect the environment.

Note: Paragraphs (2)(a) and (b), (b) and (c) do not apply to an inadvertent dealings application.

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Section 57

57 Other circumstances in which Regulator must not issue **GMO** licencethe licence

- (1) The Regulator must not <u>issue a GMO licence</u> 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 <u>issue a GMO licence</u> issue the licence unless the Regulator is satisfied that the applicant is a suitable person to hold the licence (having regard to the matters specified in section 72AM).
- (3) Subsection (2) does not apply to an inadvertent dealings application.

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

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

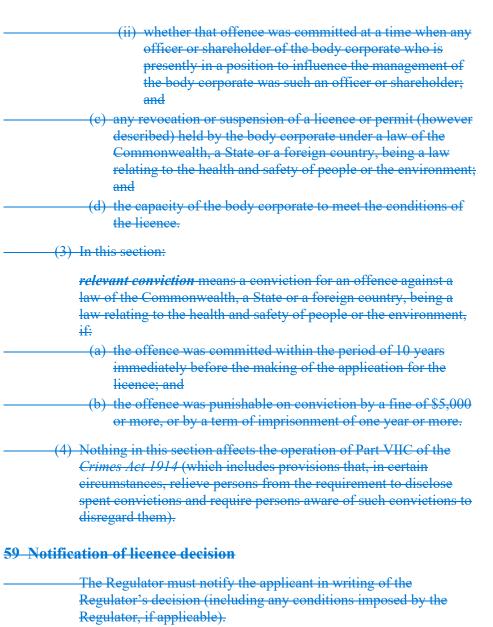
 (a) any relevant conviction of the person; and

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

 (c) the capacity of the person to meet the conditions of the licence.
 - (2) Without limiting the matters to which the Regulator may have regard in deciding whether a body corporate is a suitable person to hold a licence, the Regulator must have regard to the following:
 - (a) any relevant conviction of the body corporate; and
 - (b) if there is a relevant conviction of the body corporate:
 - (i) whether the offence concerned was committed at a time when any person who is presently a director of the body corporate was a director; and

GMO licencesLicensing system **Part 5**Decision on GMO licence applicationlicence etc. **Division 5**

Section 59



Part 5 GMO licencesLicensing systemDivision 5 Decision on GMO licence applicationlicence etc.

Section 60

60 Period of GMO licence

- (1) A GMO licence 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, unless it is cancelled or surrendered before the end of that period; that period; or
 - (b) otherwise—until it is cancelled or surrendered.
- (2) <u>A GMO licence</u> A licence is not in force throughout any period of suspension.
- (3) A licence issued as a result of an inadvertent dealings application must not be expressed to be in force for a period of longer than 12 months.

GMO licencesLicensing system Part 5 Conditions of GMO licences Division 6

Section 61

Division 6—Conditions of GMO licences

61 **GMO** licence Licence is subject to conditions

A GMO licence is subject to the following conditions:

- (a) the conditions set out in <u>Division 3 of Part 5AA sections 63</u>, 64 and 65;
- (b) any conditions specified in the rules 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 or section 71 A after the licence is issued.

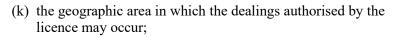
62 Conditions that may be specified prescribed or imposed

- (1) <u>GMO licence Licence</u> 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) <u>GMO licence Licence</u> 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;

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Section 63



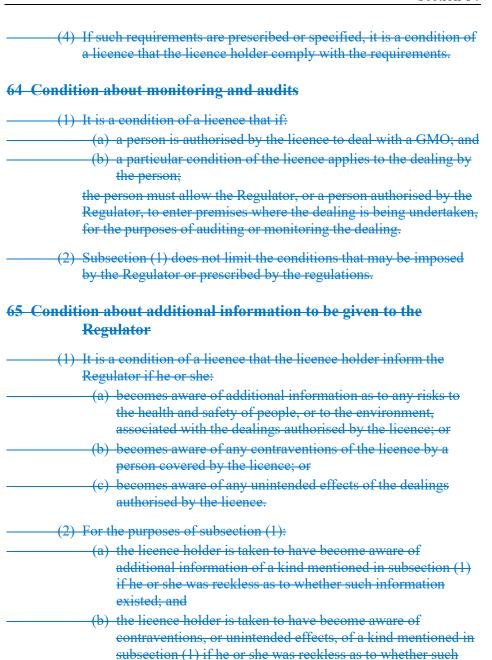
- (l) requiring compliance with the rules made for the purposes of section 27A (rules for transport, storage and disposal of GMOs);
- (l) requiring compliance with a code of practice issued under section 24, or a technical or procedural guideline issued under section 27;
- (m) supervision by, and monitoring by, Institutional Biosafety Committees;
- (n) contingency planning in respect of unintended effects of the dealings authorised by the licence;
- (o) limiting the dissemination or persistence of the GMO or its genetic material in the environment.
- (3) <u>GMO licence Licence</u> conditions may also include conditions requiring the licence holder to be adequately insured against any loss, damage, or injury that may be caused to human health, property or the environment by the licensed dealing.

63 Condition about informing people of obligations

- (1) It is a condition of a licence that the licence holder inform any person covered by the licence, to whom a particular condition of the licence applies, of the following:
 - (a) the particular condition, including any variations of it;
 - (b) the cancellation or suspension of the licence;
 - (c) the surrender of the licence.
 - (2) Requirements in relation to the manner in which information is provided under subsection (1) may be:
 - (a) prescribed by the regulations; or
 - (b) specified by the Regulator.
 - (3) Such requirements may include, but are not limited to, measures relating to labelling, packaging, conducting training and providing information.

GMO licencesLicensing system Part 5 Conditions of GMO licences Division 6

Section 64



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contraventions had occurred, or such unintended effects existed.

66 Person may give information to Regulator

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

- (a) becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or
- (b) becomes aware of any contraventions of the licence by a person covered by the licence; or
- (c) becomes aware of any unintended effects of the dealings authorised by the licence.

67 Protection of persons who give information

A person (the *first person*) does not incur any civil liability in respect of loss, damage or injury of any kind suffered by another person because the first person gave information to the Regulator under section 65, 66 or paragraph 72D(2)(h).

GMO licencesLicensing system **Part 5** Suspension, transfer, cancellation and variation of GMO licences **Division 7**

Section 68

<u>Division 7—Suspension, transfer, cancellation and</u> variation of GMO licences

Division 7—Suspension, cancellation and variation of licences

68 Suspension and cancellation of GMO licence

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

- (a) the Regulator believes on reasonable grounds that a condition of the licence has been breached, whether by the licence holder or by a person covered by the licence; or
- (b) the Regulator believes on reasonable grounds that the licence holder, or a person covered by the licence, <u>has contravened</u> this Act or a corresponding State lawhas committed an offence against this Act or the regulations; or
- (c) any annual charge payable in respect of the licence remains unpaid after the due date; or
- (d) the licence was obtained improperly; or
- (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
- (f) the Regulator is satisfied that the licence holder is no longer a suitable person to hold the licence (having regard to the matters specified in section 72AM).

69 Surrender of **GMO** licence

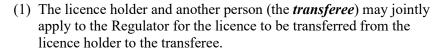
The licence holder may, with the consent of the Regulator, surrender the licence.

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Section 70

70 Transfer of GMO licences



Note: Division 1A of Part 12 sets out requirements for applications.

- (2) If the Regulator receives an application under subsection (1) to transfer the licence, the Regulator must, within the consideration period for the application, decide:
 - (a) to transfer the licence; or
 - (b) to refuse to transfer the licence.

Note: See section 178F for the consideration period for the application.

- (2) The application must be in writing, and must contain:
 - (a) such information as is prescribed by the regulations (if any);
 - (b) such information as is specified in writing by the Regulator.
- (3) The Regulator must not transfer the licence unless the Regulator is satisfied that, if the licence is transferred, any risks posed by the dealings authorised by the licence will continue to be able to be managed in such a way as to protect:
 - (a) the health and safety of people; 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 (having regard to the matters specified in section 72AM).
- (5) If the Regulator decides to transfer the licence under subsection (2), the Regulator must notify the licence holder and the transferee, in writing, of the Regulator's decision as soon as practicable after making the decision.

Note:

A decision to refuse to transfer a GMO licence is a reviewable decision (see section 179), and the Regulator must give the applicants written notice of the decision (see section 180).

GMO licencesLicensing system **Part 5** Suspension, cancellation and variation of licences **Division 7**

Section 71

- (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; and
 - (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 (unless the Regulator varies the conditions).

71 Variation of GMO licence on Regulator's initiative

- (1) The Regulator may, at any time by notice in writing given to a licence holder, vary a GMO licence.
 - Note: A decision to vary a GMO licence is a reviewable decision (see section 179), and the Regulator must give the applicant written notice of the decision (see section 180).
- (2) Without limiting subsection (1), the Regulator may:
 - (a) impose conditions to which the licence is subject; or
 - (b) remove or vary conditions to which the licence is subject and which were imposed by the Regulator; or
 - (c) extend or reduce the authority granted by the licence.
- (3) However, the Regulator must not vary the GMO licence under subsection (1) unless the Regulator is satisfied that the risks posed by the dealings proposed to be authorised by the licence as varied (the *proposed dealings*) are able to be managed in such a way as to protect:
 - (a) the health and safety of people; and
 - (b) the environment.

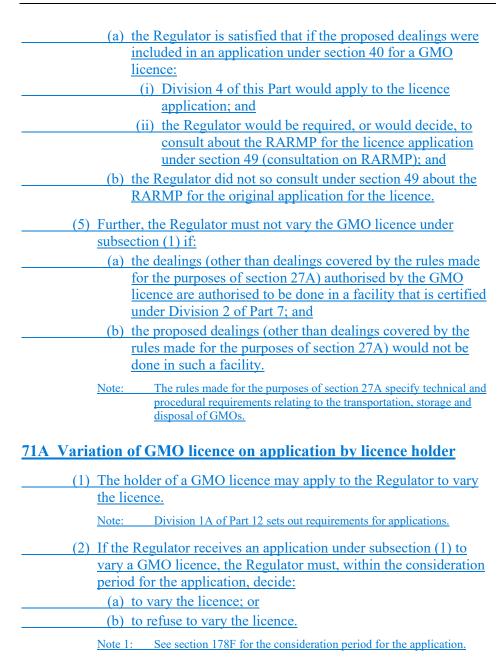
Note: Despite this subsection, the Regulator is not required to consider risks posed by the proposed dealings in certain circumstances (see section 15A).

(4) In addition, the Regulator must not vary the GMO licence under subsection (1) if:

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Section 71A



GMO licencesLicensing system **Part 5** Suspension, cancellation and variation of licences **Division 7**

Section 71A

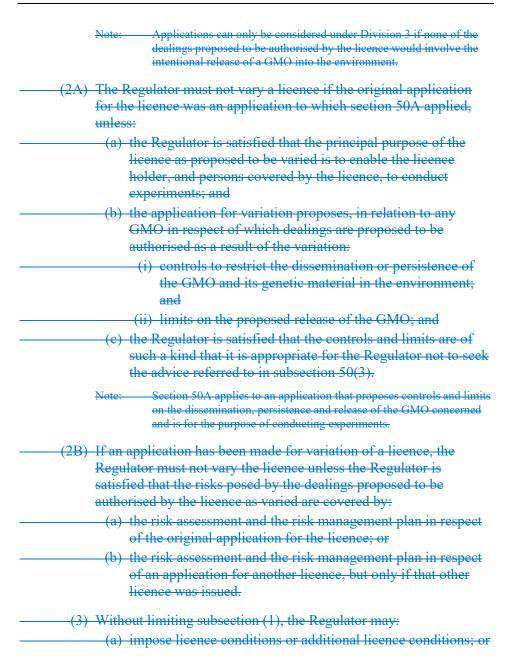
 Note 2: If the application for a variation relates to more than one aspect of the licence, the Regulator may decide to vary some or all of those aspects of the licence. Note 3: A decision to vary, or refuse to vary, a GMO licence on application by the licence holder is a reviewable decision (see section 179), and the Regulator must give the applicant written notice of the decision (see section 180). 		
(3) Without limiting subsection (1), the Regulator may:		
(a) impose conditions to which the GMO licence is subject; or		
(b) remove or vary conditions to which the licence is subject and which were imposed by the Regulator; or		
(c) extend or reduce the authority granted by the licence.		
(4) However, the Regulator must not vary the GMO licence under subsection (2) unless the Regulator is satisfied that the risks posed by the dealings proposed to be authorised by the licence as varied: (a) are able to be managed in such a way as to protect: (i) the health and safety of people; and (ii) the environment; and (b) are covered by: (i) the RARMP for the original application for the licence;		
or		
(ii) the RARMP for an application for another licence, but only if that other licence was issued.		
Note: Despite subsection (4), the Regulator is not required to consider risks posed by the dealings proposed to be authorised by the licence as varied in certain circumstances (see section 15A).		
(5) In addition, the Regulator must not vary the GMO licence under subsection (2) if:		
(a) the Regulator is satisfied that, were the dealings proposed to		
be authorised as a result of the variation to be included in an		
application under section 40 for a GMO licence:		
(i) Division 4 of this Part would apply to the licence		
application; and		

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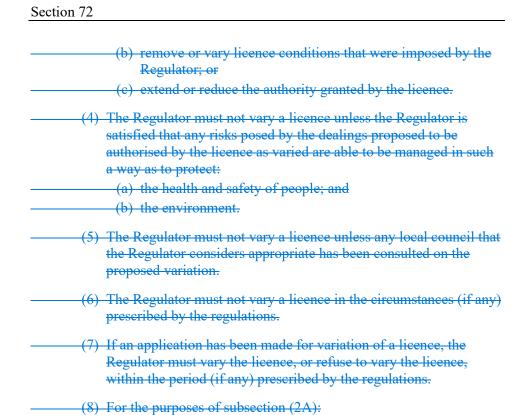
Section 71
(ii) the Regulator would be required, or would decide, to
consult about the RARMP for the licence application
under section 49 (consultation on RARMP); and
(b) the Regulator did not so consult under section 49 about the
RARMP for the original application for the licence.
(6) Further, the Regulator must not vary the GMO licence under subsection (2) if:
(a) the dealings (other than dealings covered by the rules made
for the purposes of section 27A) authorised by the GMO licence are authorised to be done in a facility that is certified under Division 2 of Part 7; and
(b) the dealings (other than dealings covered by the rules made
for the purposes of section 27A) proposed to be authorised a a result of the variation would not be done in a facility that is certified under Division 2 of Part 7.
Note: The rules made for the purposes of section 27A specify technical and procedural requirements relating to the transportation, storage and disposal of GMOs.
71 Variation of licence
(1) The Regulator may vary a licence, by notice in writing given to the licence holder:
(a) at any time, on the Regulator's own initiative; or
(b) on application by the licence-holder.
(1A) An application for a variation must be in writing, and must contain
(a) such information as is prescribed by the regulations (if any); and
(b) such information as is specified in writing by the Regulator.
(2) The Regulator must not vary a licence to authorise dealings involving the intentional release of a GMO into the environment is the application for the licence was originally considered under Division 3 of this Part.

GMO licencesLicensing system **Part 5** Suspension, cancellation and variation of licences **Division 7**

Section 71



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72 Regulator to notify of proposed suspension, cancellation or variation

controls has the same meaning as in subsection 50A(2).

limits has the same meaning as in subsection 50A(3).

- (1) Before suspending, cancelling or varying a <u>GMO</u> licence under this Division, the Regulator must give written notice of the proposed suspension, cancellation or variation to the licence holder.
- (2) The notice:
 - (a) must state that the Regulator proposes to suspend, cancel or vary the licence; and

GMO licencesLicensing system **Part 5** Suspension, cancellation and variation of licences **Division 7**

Section 72

- (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
- (c) <u>mustmay</u> invite the licence holder to make a written submission to the Regulator about the proposed suspension, cancellation or variation.
- (3) The notice must specify a period within which the licence holder:
 - (a) if the licence holder is required to give information under paragraph (2)(b)—must give the information; and
 - (a) must give the information referred to in paragraph (2)(b); and
 - (b) may make a submission under paragraph (2)(c).

The period specified must be not less than 20 business days starting on the day after the day the notice is given. The period must not end earlier than 30 days after the day on which the notice was given.

- (4) In considering whether to suspend, cancel or vary a licence, the Regulator must have regard to any submission made under paragraph (2)(c).
- (5) This section does not apply to a suspension, cancellation or variation requested by the licence holder.
- (6) This section does not apply to a suspension, cancellation or variation of a licence if the Regulator considers that the suspension, cancellation or variation is necessary in order to avoid a significant risk to human health and safety or to the environmentan imminent risk of death, serious illness, serious injury or serious damage to the environment.
- (7) This section does not apply to a variation of a licence if the Regulator is satisfied that the variation is of minor significance—or complexity.

Gene Technology Act 2000

Part 5AAA GMO permits

Division 1 Simplified outline

Section 72AA

Part 5AAA—GMO permits

Division 1—Simplified outline

72AA Simplified outline

The following is a simplified outline of this Part:

This Part provides for a permit system under which a person may apply to the Regulator for a GMO permit. A GMO permit authorises one or more permit dealings.

A dealing with a GMO is a permit dealing if it is in a class of dealings specified in the regulations to be permit dealings.

The Regulator must not issue a GMO permit unless satisfied that the person is a suitable person to hold a GMO permit and that issuing the permit would not be inconsistent with a policy principle.

A GMO permit is subject to conditions.

A GMO permit may be suspended, cancelled or surrendered.

GMO permits **Part 5AAA** Permit dealings **Division 2**

Section 72AB

Division 2—Permit dealings

72AB Permit dealings

(1)	A dealing with a GMO is a <i>permit dealing</i> if it is in a class of
	dealings specified in the regulations to be permit dealings.
(2)	Without limiting subsection (1), regulations made for the purp

- (a) specified dealings or specified kinds of dealings; or
- (b) dealings with specified GMOs or specified kinds of GMOs; or

of that subsection may specify classes of dealings by reference to:

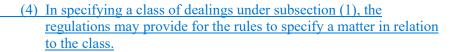
- (c) particular circumstances, including, for example:
 - (i) the purpose of the dealings; or
 - (ii) the ways in which any risks posed by the dealings are to be managed so as to protect the health and safety of people and to protect the environment; or
 - (iii) the location of the dealings; or
 - (iv) the training or experience required of a person undertaking the dealings; or
 - (v) dealings permitted or authorised under another Act.
- (3) Before the Governor-General makes regulations specifying a class of dealings to be permit dealings, the Minister must be satisfied that any risk to the health and safety of people, or to the environment, posed by any dealing in the class of dealings:
 - (a) is known; and
 - (b) can be managed through:
 - (i) requiring a permit holder to be a suitable person to hold a permit (having regard to the matters specified in section 72AM); and
 - (ii) permit conditions.

Note: Despite subsection (3), the Minister is not required to consider risks posed by a dealing in the class of dealings in certain circumstances (see section 15A).

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Part 5AAA GMO permits Division 2 Permit dealings

Section 72AB



- (5) Without limiting subsection (4), the regulations may provide for the rules to specify:
 - (a) the kind or kinds of GMOs in a class; or
 - (b) the physical containment level for GMOs in a class.
- (6) Regulations made for the purposes of subsection (4) may require the Regulator to be satisfied of, or take into account, certain matters before making rules specifying a matter in relation to a class.

GMO permits **Part 5AAA** GMO permit applications **Division 3**

Section 72AC

Division 3—GMO permit applications

72AC Person may apply for GMO permit

A person may apply to the Regulator for a GMO permit that authorises one or more specified permit dealings by a person or persons.

Note: Division 1A of Part 12 sets out requirements for applications.

Part 5AAA GMO permitsDivision 4 Decision on GMO permit application etc.

Section 72AD

Division 4—Decision on GMO permit application etc.

72AD Decision on application for GMO permit

- (1) If a person applies for a GMO permit, the Regulator must, within the consideration period for the application, decide:
 - (a) to issue the GMO permit; or
 - (b) to refuse to issue the GMO permit.
 - Note 1: See section 178F for the consideration period for the application.
 - Note 2: A decision to issue, or refuse to issue, a GMO permit authorising a specified permit dealing is a reviewable decision (see section 179), and the Regulator must give the applicant written notice of the decision (see section 180).
 - (2) The Regulator must not issue a GMO permit unless the Regulator is satisfied that the applicant is a suitable person to hold a permit (having regard to the matters specified in section 72AM).
 - (3) The Regulator must not issue a GMO permit if the Regulator is satisfied that issuing the permit would be inconsistent with a policy principle in force under section 21.

72AE GMO permit conditions

- (1) A GMO permit is subject to:
 - (a) the conditions set out in Division 3 of Part 5AA; and
 - (b) any condition specified in the rules in relation to a permit dealing authorised by the permit.
- (2) The rules must specify conditions in relation to a permit dealing authorised by a GMO permit.
 - (3) Without limiting subsection (2), the rules may specify conditions relating to any of the following:
 - (a) the scope of the dealings authorised by the GMO permit;
 - (b) the purposes for which the dealings may be undertaken;
 - (c) documentation and record-keeping requirements in relation to the dealings;

GMO permits **Part 5AAA**Decision on GMO permit application etc. **Division 4**

Section 72AF
(d) the required level of containment in respect of the dealings, including requirements relating to the certification of
facilities to specified containment levels;
(e) waste disposal requirements in relation to the dealings;
(f) measures to manage risks posed to the health and safety of people, or to the environment in relation to the dealings;
(g) data collection, including studies to be conducted, in relation
to the dealings;
(h) auditing and reporting;
(i) actions to be taken in case of the release of a GMO from a contained environment;
(j) the geographic area in which the dealings authorised by the
permit may occur;
(k) requiring compliance with the rules made for the purposes of
section 27A (rules for transport, storage and disposal of GMOs);
(1) supervision of the dealings by, or monitoring by, Institutional
Biosafety Committees;
(m) contingency planning in respect of unintended effects of the
dealings;
(n) limiting the dissemination or persistence of the GMO or its
genetic material in the environment.
72AF Period of GMO permit
(1) A GMO permit continues in force:
(a) if the permit is expressed to be in force for a particular
period—until the end of that period, unless it is cancelled or
surrendered before the end of that period; or
(b) otherwise—until it is cancelled or surrendered.
(2) A GMO permit is not in force throughout any period of suspension.

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Part 5AAA GMO permits

Division 5 Suspension, cancellation and surrender of GMO permits

Section 72AG

Division 5—Suspension, cancellation and surrender of **GMO** permits

72AG Suspension and cancellation of GMO permit The Regulator may, by notice in writing given to a permit holder, suspend or cancel a GMO permit if: (a) the Regulator believes on reasonable grounds that a condition of the permit has been breached, whether by the permit holder or by a person covered by the permit; or (b) the Regulator believes on reasonable grounds that the permit holder, or a person covered by the permit, has contravened this Act or a corresponding State law; or (c) any annual charge payable in respect of the permit remains unpaid after the due date; or (d) the permit was obtained improperly; or (e) the Regulator becomes aware of risks associated with the continuation of the permit dealings authorised by the permit, and is satisfied that the permit holder has not proposed, or is not in a position to implement, adequate measures to deal with those risks; or (f) the Regulator is satisfied that the permit holder is no longer a suitable person to hold the permit (having regard to the matters specified in section 72AM). 72AH Regulator to notify permit holder of proposed suspension or

cancellation

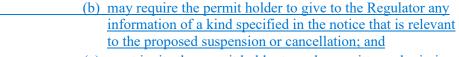
(1) Before suspending or cancelling a GMO permit under this Division, the Regulator must give written notice of the proposed suspension or cancellation to the permit holder.

(2) The notice:

(a) must state that the Regulator proposes to suspend or cancel the permit; and

GMO permits **Part 5AAA**Suspension, cancellation and surrender of GMO permits **Division 5**

Section 72AJ



- (c) must invite the permit holder to make a written submission to the Regulator about the proposed suspension or cancellation.
- (3) The notice must specify a period within which the permit holder:
 - (a) if the permit holder is required to give information under paragraph (2)(b)—must give the information; and
 - (b) may make a submission under paragraph (2)(c). The period specified must be not less than 20 business days starting on the day after the day the notice is given.
- (4) In considering whether to suspend or cancel a GMO permit, the Regulator must have regard to any submission made in response to an invitation under paragraph (2)(c).
- (5) This section does not apply to a suspension or cancellation of a

 GMO permit if the Regulator considers that the suspension or
 cancellation is necessary in order to avoid a significant risk to
 human health and safety or to the environment.

72AJ Surrender of GMO permit

A permit holder may, with the consent of the Regulator, surrender the GMO permit.

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Part 5AA Other matters relating to GMO licences and GMO permitsDivision 1 Outline and operation of this Part

Section 72AK

Part 5AA—Other matters relating to GMO licences and GMO permits

Division 1—Outline and operation of this Part

72AK Simplified outline

The following is a simplified outline of this Part:

This Part sets out the matters that must be taken into account by the Regulator when deciding whether a person is suitable to hold a GMO licence or GMO permit.

<u>It also sets out some of the conditions of GMO licences and GMO permits.</u>

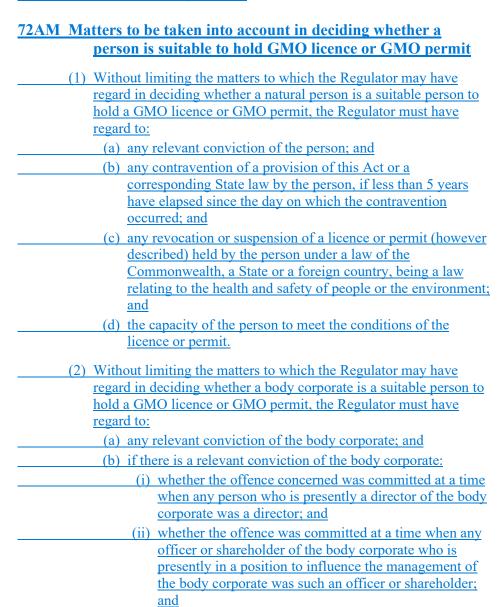
72AL Application of this Part

This Part applies in relation to GMO licences and GMO permits.

Other matters relating to GMO licences and GMO permits **Part 5AA**Suitable persons **Division 2**

Section 72AM

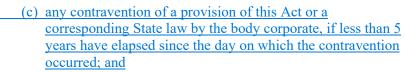
Division 2—Suitable persons



Gene Technology Act 2000

Part 5AA Other matters relating to GMO licences and GMO permitsDivision 2 Suitable persons





- (d) any revocation or suspension of a licence or permit (however described) held by the body corporate under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment; and
- (e) the capacity of the body corporate to meet the conditions of the licence or permit.
- (3) Nothing in this section affects the operation of Part VIIC of the Crimes Act 1914 (which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them).

Other matters relating to GMO licences and GMO permits **Part 5AA**Conditions of GMO licences and GMO permits **Division 3**

Section 72AN

<u>Division 3—Conditions of GMO licences and GMO</u> permits

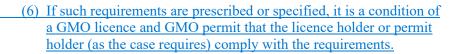
72AN Conditions about informing people of obligations (1) It is a condition of a GMO licence that the licence holder inform any person covered by the licence and to whom any of the following conditions apply, of the condition, including any variations of it: (a) a condition imposed by the Regulator at the time of issuing the licence; (b) a condition imposed by the Regulator under section 71 or 71A after the licence is issued. (2) It is a condition of a GMO licence and GMO permit that the licence holder or permit holder (as the case requires) inform any person who ceases to be authorised by the licence or permit to deal with a GMO of that cessation. A person may cease to be authorised by a GMO licence or GMO permit to deal with a GMO if, for example, the licence or permit is suspended or cancelled. (3) The licence holder or permit holder (as the case requires) must inform the person of a matter in subsection (1) or (2): (a) within the period specified by the Regulator; or (b) if no period is specified—as soon as reasonably practicable after the licence holder or permit holder knows about the matter.

- (4) Requirements in relation to the manner in which information is provided under subsection (1) or (2) may be:
 - (a) specified in the rules; or
 - (b) specified by the Regulator.
- (5) Such requirements may include, but are not limited to, measures relating to labelling, packaging, conducting training and providing information.

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Part 5AA Other matters relating to GMO licences and GMO permitsDivision 3 Conditions of GMO licences and GMO permits

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(7) If a GMO licence or GMO permit is not in force, the conditions under subsections (1), (2) and (6) (if any) continue to apply in relation to the former licence holder or former permit holder as if the former holder were still the holder.

72ANA Condition about record keeping during suspension

If a condition of a GMO licence or GMO permit requires a licence holder or permit holder to make or maintain a record of dealings with a GMO, that condition continues to apply in relation to the holder during any period during which the licence or permit (as the case requires) is suspended.

72AP Condition about monitoring

- (1) It is a condition of a GMO licence and GMO permit that if:
 - (a) a person is authorised by the licence or permit to deal with a GMO; and
 - (b) any of the following conditions of the licence or permit applies to the dealing by the person:
 - (i) a condition specified in the rules;
 - (ii) a condition imposed by the Regulator at the time of issuing the licence;
 - (iii) a condition imposed by the Regulator under section 71 or 71A after the licence is issued;

the person must permit an authorised inspector to enter, at a reasonable time, premises where the dealing has been, or is being, undertaken, for one or more of the following purposes:

- (c) determining whether a provision subject to monitoring under Part 10 has been, or is being, complied with;
- (d) determining whether information subject to monitoring under Part 10 is correct.
- (2) Subsection (1) does not limit the conditions that may be:

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Other matters relating to GMO licences and GMO permits **Part 5AA**Conditions of GMO licences and GMO permits **Division 3**

Section 72AQ (a) imposed by the Regulator for GMO licences; or (b) specified in the rules under paragraph 61(b) for GMO licences; or (c) specified in the rules under subsection 72AE(2) for permit dealings authorised by a GMO permit. 72AQ Condition about information to be given to the Regulator (1) It is a condition of a GMO licence and GMO permit that the licence holder or permit holder (as the case requires) inform the Regulator if the holder becomes aware of: (a) information in relation to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence or permit; or (b) any contraventions of the licence or permit by a person covered by the licence or permit; or (c) any unintended effects of the dealings authorised by the licence or permit. (2) The licence holder or permit holder must inform the Regulator of a matter in paragraph (1)(a), (b) or (c) within 48 hours of the holder becoming aware of the matter. (3) For the purposes of subsections (1) and (2): (a) the licence holder or permit holder is taken to have become aware of information of a kind mentioned in subsection (1) if the holder was reckless as to whether such information existed; and (b) the licence holder or permit holder is taken to have become aware of contraventions, or unintended effects, of a kind mentioned in subsection (1) if the holder was reckless as to whether such contraventions had occurred, or such unintended effects existed. 72AR Person may give information to Regulator A person covered by a GMO licence or GMO permit may inform

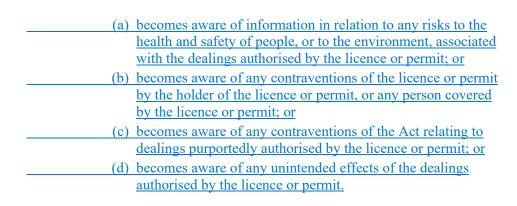
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the Regulator if the person:

Part 5AA Other matters relating to GMO licences and GMO permitsDivision 3 Conditions of GMO licences and GMO permits

Section 72AR



Emergency dealing determinations Part 5A
Simplified outline Division 1

Section 72A

Part 5A—Emergency dealing determinations

Division 1—Simplified outline

72A Simplified outline

The following is a simplified outline of this Part:

This Part provides a system under which the Minister can make determinations relating to dealings with GMOs in emergencies.

Part 5A Emergency dealing determinationsDivision 2 Making of emergency dealing determination

Section 72B

Division 2—Making of emergency dealing determination

72B Minister may make emergency dealing determination

- (1) The Minister may, by legislative instrument (an *emergency dealing determination*), specify dealings with a GMO for the purposes of this Part.
- (2) The Minister may make an emergency dealing determination only if:
 - (a) the Minister has received advice from:
 - (i) the Commonwealth Chief Medical Officer; or
 - (ii) the Commonwealth Chief Veterinary Officer; or
 - (iii) the Commonwealth Chief Plant Protection Officer; or
 - (iv) a person prescribed by the regulations; that there is an actual or imminent threat to the health and safety of people or to the environment, and that the dealings proposed to be specified in the emergency dealing determination would, or would be likely to, adequately address the threat; and
 - (b) the Minister is satisfied that there is an actual or imminent threat to the health and safety of people or to the environment, and that the dealings proposed to be specified in the emergency dealing determination would, or would be likely to, adequately address the threat; and
 - (c) the Minister has received advice from the Regulator that any risks posed by the dealings proposed to be specified in the emergency dealing determination are able to be managed in such a way as:
 - (i) to protect the health and safety of people; and
 - (ii) to protect the environment; and
 - (d) the Minister is satisfied that any risks posed by the dealings proposed to be specified in the emergency dealing determination are able to be managed in such a way as:
 - (i) to protect the health and safety of people; and
 - (ii) to protect the environment; and

Emergency dealing determinations Part 5A Making of emergency dealing determination Division 2

Section 72C

- (e) the States have been consulted in relation to the making of the proposed emergency dealing determination.
- Note 1: Despite paragraph (2)(c), the Regulator is not required to give advice in relation to risks posed by the dealings proposed to be specified in the emergency dealing determination in certain circumstances (see section 15A).
- Note 2: Despite paragraph (2)(d), the Minister is not required to consider risks posed by the dealings proposed to be specified in the emergency dealing determination in certain circumstances (see section 15A).
- (3) An actual or imminent threat of a kind mentioned in paragraph (2)(a) or (b) may include, but is not limited to, any of the following:
 - (a) a threat from the outbreak of a plant, animal or human disease;
 - (b) a threat from a particular plant or animal, such as a pest or an alien invasive species;
 - (c) a threat from an industrial spillage.
- (4) The dealings in respect of which the Minister may make an emergency dealing determination may be:
 - (a) all dealings with a GMO or with a specified class of GMOs; or
 - (b) a specified class of dealings with a GMO or with a specified class of GMOs; or
 - (c) one or more specified dealings with a GMO or with a specified class of GMOs.
- (5) Section 42 (disallowance) of the *Legislation Act 2003* does not apply to an emergency dealing determination.

72C Period of effect of emergency dealing determination

- (1) An emergency dealing determination takes effect:
 - (a) on the day on which the emergency dealing determination is made; or
 - (b) on a later day that is specified in the emergency dealing determination.

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Part 5A Emergency dealing determinations

Division 2 Making of emergency dealing determination

Section 72C

- (2) An emergency dealing determination ceases to have effect:
 - (a) subject to subsection (3), at the end of the period of 6 months starting when the emergency dealing determination takes effect; or
 - (b) at the end of the period specified by the Minister in the emergency dealing determination; or
 - (c) when the emergency dealing determination is revoked; whichever occurs first.
- (3) The Minister may, by legislative instrument, extend the period of effect of an emergency dealing determination.
- (4) The Minister may extend the period of effect of an emergency dealing determination under subsection (3) more than once, but each single such extension must not exceed 6 months.
- (5) The Minister may extend the period of effect of an emergency dealing determination only if:
 - (a) the Minister has received advice from the original adviser in relation to the emergency dealing determination that the threat to which the determination relates still exists, and that the proposed extension would, or would be likely to, adequately address the threat; and
 - (b) the Minister is satisfied that the threat still exists, and that the proposed extension would, or would be likely to, adequately address that threat; and
 - (c) the Minister has received advice from the Regulator that any risks posed by the proposed extension are able to be managed in such a way as:
 - (i) to protect the health and safety of people; and
 - (ii) to protect the environment; and
 - (d) the Minister is satisfied that any risks posed by the proposed extension are able to be managed in such a way as:
 - (i) to protect the health and safety of people; and
 - (ii) to protect the environment; and
 - (e) a majority of jurisdictions agree to the extension.

Emergency dealing determinations Part 5A Making of emergency dealing determination Division 2

Section 72C

Note: Despite subsection (5), the Minister and Regulator are not required to consider risks posed by the dealings proposed to be authorised by the GMO licence in certain circumstances (see section 15A).

- (6) A legislative instrument extending the period of effect of an emergency dealing determination takes effect at the time when the determination would have ceased to have effect but for the extension.
- (6A) Section 42 (disallowance) of the *Legislation Act 2003* does not apply to an extension of the period of effect of an emergency dealing determination.
 - (7) In subsection (5):

original adviser, in relation to an emergency dealing determination, means the person who gave the advice mentioned in paragraph 72B(2)(a) in relation to the determination.

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Part 5A Emergency dealing determinations

Division 3 Conditions Effect and conditions of emergency dealing determination

Section 72D

Division 3—<u>Conditions</u> <u>Effect and conditions</u> of emergency dealing determination

72D Emergency dealing determination <u>may beauthorises dealings</u>, subject to conditions

- (1) An emergency dealing determination is subject to the conditions specified in the determination (if any), and the condition set out in subsection (4) if applicable.
- (1) If an emergency dealing determination is in force in respect of dealings with a GMO, those dealings are authorised, subject to the conditions (if any) specified in the emergency dealing determination.
- (2) Conditions may relate to, but are not limited to, the following:
 - (a) the quantity of GMO in relation to which dealings are covered;
 - (b) the scope of the dealings covered;
 - (c) the purposes for which the dealings may be undertaken;
 - (d) variations to the scope or purposes of the dealings;
 - (e) the source of the GMO;
 - (f) the persons who may deal with the GMO;
 - (g) the information that is required to be given by a person and the person to whom that information is to be given;
 - (h) obligations about informing the Regulator if:
 - (i) a person becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings specified in the emergency dealing determination; or
 - (ii) a person becomes aware of any contraventions of the conditions to which the emergency dealing determination is subject by any person; or
 - (iii) a person becomes aware of any unintended effects of the dealings specified in the emergency dealing determination;

Emergency dealing determinations Part 5A ConditionsEffect and conditions of emergency dealing determination Division 3

Section 72D

- (i) the storage and security of the GMO;
- (j) the required level of containment in respect of the dealings, including requirements relating to the certification of facilities to specified containment levels;
- (k) waste disposal requirements;
- (l) the manner in which any quantity of the GMO is to be dealt with if a condition of the emergency dealing determination is breached;
- (m) measures to manage risks posed to the health and safety of people, or to the environment;
- (n) data collection, including studies to be conducted;
- (o) auditing and reporting;
- (p) the keeping and disclosure of, and access to, records about the GMO;
- (q) actions to be taken in case of the release of a GMO from a contained environment;
- (r) the geographic area in which the dealings specified in the emergency dealing determination may occur;
- (s) requiring compliance with the rules made for the purposes of section 27A (rules for transport, storage and disposal of GMOs);
- (s) requirements for compliance with a code of practice issued under section 24, or a technical or procedural guideline issued under section 27;
- (t) supervision by, and monitoring by, Institutional Biosafety Committees;
- (u) contingency planning in respect of unintended effects of the dealings specified in the emergency dealing determination;
- (v) limiting the dissemination or persistence of the GMO or its genetic material in the environment;
- (w) any other matters that the Minister thinks appropriate.
- (3) A condition under paragraph (2)(f) may permit dealings with a GMO by, or may impose obligations upon:
 - (a) a specified person or persons; or
 - (b) a specified class of person.

Part 5A Emergency dealing determinations

Division 3 Conditions Effect and conditions of emergency dealing determination

Section 72D



- (a) a person undertakes a dealing specified in the emergency dealing determination; and
- (b) a condition (other than this condition) applies to the dealing by the person;

the person must permit an authorised inspector to enter, at a reasonable time, premises where the dealing has been, or is being, undertaken for one or more of the following purposes:

- (c) determining whether a provision subject to monitoring under Part 10 has been, or is being, complied with;
- (d) determining whether information subject to monitoring under Part 10 is correct.
- (4) It is a condition of an emergency dealing determination that if:
 - (a) a dealing with a GMO is specified in the emergency dealing determination; and
 - (b) a particular condition of the emergency dealing determination applies to the dealing by a person;

the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

(5) Subsection (4) does not limit the conditions that may be specified in an emergency dealing determination.

Emergency dealing determinations Part 5A Variation, suspension and revocation of emergency dealing determination **Division 4**

Section 72E

Division 4—Variation, suspension and revocation of emergency dealing determination

72E Variation, suspension and revocation of emergency dealing determination

- (1) The Minister may, by legislative instrument, vary the conditions to which an emergency dealing determination is subject, including by imposing new conditions.
- (2) The Minister may, by legislative instrument, suspend or revoke an emergency dealing determination if:
 - (a) the Minister becomes aware of risks to the health and safety of people, or to the environment, associated with the continuation of the dealings authorised by the emergency dealing determination, and is satisfied that adequate measures to address those risks are not able to be implemented; or
 - (b) the Minister is satisfied that the threat to which the emergency dealing determination relates:
 - (i) no longer exists; or
 - (ii) is no longer sufficiently actual or imminent as to require the determination to be in force to address that threat; or
 - (c) the Minister is no longer satisfied that the dealings specified in the emergency dealing determination adequately address the threat.
- (3) The Minister must not:
 - (a) vary an emergency dealing determination (unless the variation is of a minor technical nature); or
 - (b) suspend or revoke an emergency dealing determination; unless the States have been consulted in relation to the variation, suspension or revocation, as the case requires.
- (4) A variation, suspension or revocation of an emergency dealing determination takes effect:
 - (a) if the Minister states in the variation, suspension or revocation that the variation, suspension or revocation is

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Part 5A Emergency dealing determinations

Division 4 Variation, suspension and revocation of emergency dealing determination

Section 72E

necessary to prevent significant risk to human health and safety or to the environmentimminent risk of death, serious illness, serious injury or serious environmental damage—on the day on which the variation, suspension or revocation is made; or

- (b) in any other case—on the day specified by the Minister in the variation, suspension or revocation.
- (5) The day specified as mentioned in paragraph (4)(b) must not be earlier than 20 business days 30 days after the day on which the variation, suspension or revocation is made.
- (6) Section 42 (disallowance) of the *Legislation Act 2003* does not apply to a variation, suspension or revocation of an emergency dealing determination.

Notifiable dealings, non-notifiable dealings and dealings on the GMO Register Part 6
Simplified outline Division 1

Section 73

Part 6—Notifiable dealings, non-notifiable dealings and dealings on the GMO Register

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

Division 1—Simplified outline

73 Simplified outline

The following is a simplified outline of this Part:

Divisions 2 and 2AA of this Part establish a system to regulate notifiable dealings. A dealing with a GMO is a notifiable dealing if it is in a class of dealings specified in the regulations to be notifiable dealings.

The Regulator must be notified about notifiable dealings.

Some notifiable dealings have authorisation requirements, which are specified in the regulations.

Notifiable dealings are subject to conditions.

<u>Division 2A of this Part relates to non-notifiable dealings. A</u> <u>dealing with a GMO is a non-notifiable dealing if it is in a class of</u> dealings specified in the regulations to be non-notifiable dealings.

Division 3 of this Part establishes the GMO Register.

The Regulator may determine that certain dealings are to be included on the GMO Register. If a dealing is included on the GMO Register, anyone may undertake the dealing, subject to any specified conditions.

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Part 6 Regulation of notifiable low risk dealings and dealings on the GMO Register **Division 1** Simplified outline

Section 73

The GMO Register must be made publicly available on the internet.

73 Simplified outline

The following is a simplified outline of this Part:

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

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

Division 3 of this Part establishes the GMO Register.

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

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

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

Notifiable dealings Division 2

Section 74

Division 2—Notifiable dealings

74 Notifial	ble dealings	
(1)	A dealing with a GMO is a notifiable dealing if it is in a class	S

(2) Without limiting subsection (1), regulations made for the purposes of that subsection may specify classes of dealings by reference to:

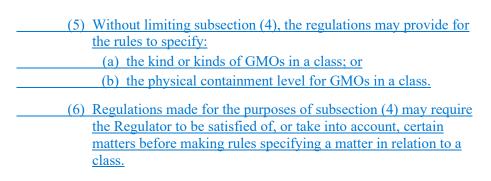
dealings specified in the regulations to be notifiable dealings.

- (a) specified dealings or specified kinds of dealings; or
- (b) dealings with specified GMOs or specified kinds of GMOs; or
- (c) particular circumstances, including, for example:
 - (i) the purpose of the dealings; or
 - (ii) the ways in which any risks posed by the dealings are to be managed so as to protect the health and safety of people and to protect the environment; or
 - (iii) the location of the dealings; or
 - (iv) the training or experience required of a person undertaking the dealings; or
 - (v) dealings permitted or authorised under another Act.
- (3) Before the Governor-General makes regulations specifying a class of dealings to be notifiable dealings, the Minister must be satisfied that any risk to the health and safety of people, or to the environment, posed by any dealing in the class of dealings:
 - (a) is known; and
 - (b) can be managed through the authorisation requirements (if any) or conditions relating to the dealing.
 - Note: Despite subsection (3), the Minister is not required to consider risks posed by a dealing in the class of dealings in certain circumstances (see section 15A).
- (4) In specifying a class of dealings under subsection (1), the regulations may provide for the rules to specify a matter in relation to the class.

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Part 6 Regulation of notifiable low risk dealings and dealings on the GMO Register Division 2 Notifiable dealings

Section 75



75 Authorisation requirements

- (1) If, under subsection 74(1), the regulations specify a class of dealings to be notifiable dealings, the regulations may specify any of the following requirements relevant to the notifiable dealing:
 - (a) the actions (if any) required to be undertaken by an

 Institutional Biosafety Committee in relation to the class of
 notifiable dealing;
 - (b) that a person must notify the Regulator about a notifiable dealing in the class before the dealing is undertaken;
 - (c) any other requirement relevant to the notifiable dealing.
 - (2) If the regulations specify the matter referred to in paragraph (1)(b), the regulations must also specify any of the following requirements for the notifiable dealing:
 - (a) the person (the *relevant notifier*) who must notify Regulator about the notifiable dealing:
 - (b) the period in which the relevant notifier must notify the Regulator about the dealing:
 - (c) the form the notification must take (which may be in a form approved by the Regulator);
 - (d) the documents or information that must accompany the notification (if any) (which may be specified in writing by the Regulator);
 - (e) the notification fee (if any) that must accompany the notification.

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

Notifiable dealings Division 2

Section 75

(3) The requirements specified by the regulations for the purposes of this section for a notifiable dealing in a class of notifiable dealings are the *authorisation requirements* for the notifiable dealing.

Gene Technology Act 2000

Part 6 Regulation of notifiable low risk dealings and dealings on the GMO Register Division 2AA Conditions of notifiable dealings

Section 75A

Division 2AA—Conditions of notifiable dealings

75A Conditions of notifiable dealings

- (1) A notifiable dealing in a class of notifiable dealings is subject to:
 - (a) the conditions in this Division; and
 - (b) any condition specified in the rules in relation to the class.
- (2) Without limiting paragraph (1)(b), the rules may specify conditions relating to any of the following:
 - (a) the location or facilities at which the dealings must occur;
 - (b) the training or expertise required of persons undertaking dealings.

75B Condition about monitoring

It is a condition of a notifiable dealing that if:

- (a) a person undertakes the dealing; and
- (b) a condition (other than this condition) applies to the dealing by the person;

the person must permit an authorised inspector to enter, at a reasonable time, premises where the dealing has been, or is being, undertaken for one or more of the following purposes:

- (a) determining whether a provision subject to monitoring under Part 10 has been, or is being, complied with;
- (b) determining whether information subject to monitoring under Part 10 is correct.

75C Condition about notification—certain notifiable dealings

- (1) It is a condition of a notifiable dealing that if a person is not required to notify the Regulator about the dealing before the dealing is undertaken under paragraph 75(1)(b), a person must notify the Regulator about the notifiable dealing at another time.
- (2) The rules must specify the following:

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

Conditions of notifiable dealings Division 2AA

Section 75D

- (a) the person (the *relevant notifier*) who must notify Regulator about the notifiable dealing;
 - (b) the period in which the relevant notifier must notify the Regulator about the dealing;
 - (c) the form the notification must take (which may be in a form approved by the Regulator);
 - (d) the documents or information that must accompany the notification (which may be specified in writing by the Regulator);
 - (e) the notification fee (if any) that must accompany the notification.
- (3) If the condition in subsection (1) applies to a notifiable dealing, it is a condition of the notifiable dealing that the relevant notifier must comply with the requirements specified by the rules for the purposes of this section.

75D Person may give information to Regulator

A person undertaking a notifiable dealing may inform the Regulator if the person becomes aware of:

- (a) information in relation to any risks to the health and safety of people, or to the environment, associated with the notifiable dealing; or
- (b) any contravention of an authorisation requirement for the notifiable dealing; or
- (c) any contravention of a condition of the notifiable dealing; or
- (d) any contravention of the Act by any person in relation to the notifiable dealing; or
- (e) any unintended effects of the notifiable dealing.

Gene Technology Act 2000

Part 6 Regulation of notifiable low risk dealings and dealings on the GMO Register **Division 2A** Non-notifiable dealings

Section 75E

Division 2A—Non-notifiable dealings

75E Non-notifiable dealings

- (1) A dealing with a GMO is a *non-notifiable dealing* if it is in a class of dealings specified in the regulations to be non-notifiable dealings.
 - (2) Without limiting subsection (1), regulations made for the purposes of that subsection may specify classes of dealings by reference to:
 - (a) specified dealings or specified kinds of dealings; or
 - (b) dealings with specified GMOs or specified kinds of GMOs;
 - (c) particular circumstances, including, for example:
 - (i) the purpose of the dealings; or
 - (ii) the ways in which any risks posed by the dealings are to be managed so as to protect the health and safety of people and to protect the environment; or
 - (iii) the location of the dealings; or
 - (iv) the training or experience required of a person undertaking the dealings; or
 - (v) dealings permitted or authorised under another Act.
 - (3) Before the Governor-General makes regulations specifying a class of dealings to be non-notifiable dealings, the Minister must be satisfied that any risk to the health and safety of people, or to the environment, posed by any dealing in the class of dealings:
 - (a) is known; and
 - (b) can be managed without conditions relating to the dealing.
 - Note: Despite subsection (3), the Minister is not required to consider risks posed by a dealing in the class of dealings in certain circumstances (see section 15A).
 - (4) In specifying a class of dealings under subsection (1), the regulations may provide for the rules to specify a matter in relation to the class.

Regulation of notifiable low risk dealings and dealings on the GMO Register **Part 6**Non-notifiable dealings **Division 2A**

Section 75E

- (5) Without limiting subsection (4), the regulations may provide for the rules to specify:
 - (a) the kind or kinds of GMOs in a class; or
 - (b) the physical containment level for GMOs in a class.
- (6) Regulations made for the purposes of subsection (4) may require the Regulator to be satisfied of, or take into account, certain matters before making rules specifying a matter in relation to a class.

Gene Technology Act 2000

Part 6 Regulation of notifiable low risk dealings and dealings on the GMO RegisterDivision 2 Notifiable low risk dealings

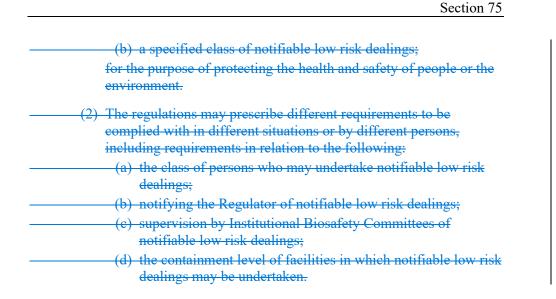
Section 74

Division 2—Notifiable low risk dealings

74 Notifiable low risk dealings (1) The regulations may declare a dealing with a GMO to be a notifiable low risk dealing for the purposes of this Act. (2) Before the Governor-General makes regulations declaring a dealing with a GMO to be a notifiable low risk dealing, the Regulator must be satisfied that the dealing would not involve the intentional release of a GMO into the environment. (3) Before the Governor-General makes regulations declaring a dealing with a GMO to be a notifiable low risk dealing, the Regulator must consider: (a) whether the dealing with the GMO would involve any risk to the health and safety of people, or to the environment, taking into account: (i) the properties of the GMO as a pathogen or pest; and (ii) the toxicity of any proteins produced by the GMO; and (b) if there is such a risk whether one or more of the requirements prescribed in the regulations for the purposes of subsection 75(2) would be sufficient to manage that risk; and (c) any other matter the Regulator considers appropriate. (4) Regulations under subsection (1) may be expressed to apply to: (a) all dealings with a GMO or with a specified class of GMOs; (b) a specified class of dealings with a GMO or with a specified class of GMOs; 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: (a) a specified notifiable low risk dealing; or

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

Notifiable low risk dealings Division 2



Gene Technology Act 2000

Part 6 Regulation of notifiable low risk dealings and dealings on the GMO Register Division 3 The GMO Register

Section 76

Division 3—The GMO Register

76 GMO Register

- (1) There is to be a Register known as the GMO Register.
- (2) The GMO Register is to be maintained by the Regulator.
- (3) The GMO Register must be made available for public inspection on the internet.
- (3) The GMO Register may be kept in a computerised form.

77 Contents of Register

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

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

78 Regulator may include dealings with GMOs on GMO Register

- (1) The Regulator may, by legislative instrument, determine that a dealing with a GMO is to be included on the GMO Register if the Regulator is satisfied that:
 - (a) the dealing is, or has been:
 - (i) authorised by a GMO licence; or
 - (ii) authorised by a GMO permit; or
 - (b) the GMO concerned would be a GM product if it were not specified in regulations, made under paragraph 12C(c), to be a genetically modified organism; or
 - (c) the dealing satisfies criteria prescribed by the regulations.
 - (a) the dealing is, or has been, authorised by a GMO licence; or
 - (b) the GMO concerned:
 - (i) is a GM product; and

Regulation of notifiable low risk dealings and dealings on the GMO Register **Part 6**The GMO Register **Division 3**

Section 79

- (ii) is a genetically modified organism only because of regulations made under paragraph (c) of the definition of genetically modified organism.
- (2) A determination under subsection (1) may be made:
 - (a) on application by the holder of <u>a GMO licence or GMO</u> <u>permita licence</u> that authorises the dealing; or
 - (b) on the initiative of the Regulator.

Note: Division 1A of Part 12 sets out requirements for applications.

- (3) A determination under subsection (1) comes into effect on the day specified in the determination.
- (4) Section 42 (disallowance) of the *Legislation Act 2003* does not apply to a determination under subsection (1).

79 Regulator not to make determination unless risks can be managed

- (1) The Regulator must not make a determination under subsection 78(1) in respect of a dealing with a GMO unless the Regulator is satisfied:
 - (a) that any risks posed by the dealing to the health and safety of people or to the environment are minimal; and
 - (b) that it is not necessary for persons undertaking the dealing to hold or be covered by a GMO licence or GMO permithold, or be covered by a GMO licence, in order to protect the health and safety of people or to protect the environment.

Note: Despite subsection (1), the Regulator is not required to consider risks posed by the dealings in certain circumstances (see section 15A).

- (2) For the purposes of subsection (1), the Regulator must have regard to the following:
 - (a) any data available to the Regulator about adverse effects posed by the dealing;
 - (b) any other information as to risks to the health and safety of people or to the environment associated with the dealing of which the Regulator is aware, including information provided

Part 6 Regulation of notifiable low risk dealings and dealings on the GMO RegisterDivision 3 The GMO Register

Section 80

- to the Regulator by the holder of a GMO licence or a GMO permit under section 72AQ or by another person under section 72ARa licence holder under section 65 or by another person under section 66;
- (c) whether there is a need for the dealing to be subject to conditions in order to manage risks to the health and safety of people or to the environment;
- (d) any other information in relation to whether the dealing should be authorised by a GMO licence or GMO permit.
- (3) The Regulator may have regard to such other matters as the Regulator considers relevant.

80 Variation of GMO Register

- (1) The Regulator may, by legislative instrument, vary the GMO Register.
- (2) A variation may:
 - (a) remove a dealing from the GMO Register; or
 - (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 GMO Register is subject.
- (3) Section 42 (disallowance) of the *Legislation Act 2003* does not apply to a variation under subsection (1).

81 Inspection of Register

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

Certification and accreditation **Part 7**Simplified outline **Division 1**

Section 82

Part 7—Certification and accreditation

Division 1—Simplified outline

82 Simplified outline

The following is a simplified outline of this Part:

Division 2 of this Part establishes a system under which the Regulator may certify facilities to particular containment levels. The rules may specify requirements for the certification of facilities to particular containment levels.

<u>Division 3 of this Part enables the Regulator to accredit</u> <u>organisations. The rules may specify requirements that must be met in order for an organisation to be accredited under this Division.</u>

Conditions to which a GMO licence, a GMO permit, an emergency dealing determination or a notifiable dealing may be subject may:

- (a) require that facilities be certified to particular containment levels; or
- (b) specify that dealings must be supervised by an

 Institutional Biosafety Committee established by an
 accredited organisation.

Authorisation requirements for notifiable dealings may also specify such matters.

82 Simplified outline

The following is a simplified outline of this Part:

Division 2 of this Part establishes a system under which the Regulator may certify facilities to specified containment levels in accordance with guidelines issued by the Regulator. Licence conditions, or conditions to which an emergency dealing

Gene Technology Act 2000

Part 7 Certification and accreditationDivision 1 Simplified outline

Section 82

determination is subject, can require that facilities be certified to specified containment levels.

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

Certification and accreditation Part 7
Certification Division 2

Section 83

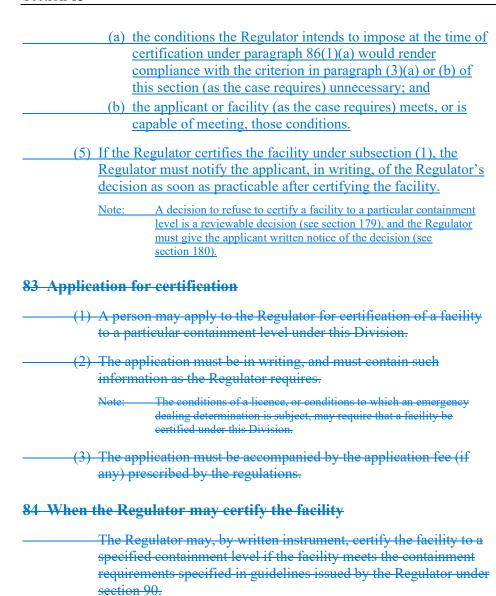
Division 2—Certification

83 Application for certification
A person may apply to the Regulator for certification of a facility
to a particular containment level under this Division.
Note: Division 1A of Part 12 sets out requirements for applications.
84 Decision on application for certification
(1) If a person applies for certification of a facility, the Regulator
must, within the consideration period for the application, decide:
(a) to certify the facility to a particular containment level; or
(b) to refuse to certify the facility.
Note: See section 178F for the consideration period for the application.
(2) If the Regulator certifies the facility to a particular containment
level, the Regulator may decide that the facility is only certified for
a particular period.
(3) Subject to subsection (4), when deciding whether to certify the
facility to a particular containment level, the Regulator must be
satisfied that:
(a) the facility meets the containment requirements specified in
the rules made under section 90; and
(b) the facility or applicant meets any other criteria for
certification specified in the rules made under section 90; and
(c) the applicant:
(i) has authority to admit or exclude other persons from the
premises; and
(ii) has authority to maintain the facility, including the
fittings and equipment within the facility; and
(iii) is capable of meeting the conditions of the certification.
(4) The Regulator is not required to be satisfied of a criterion in
paragraph (3)(a) or (b) if the Regulator is satisfied that:

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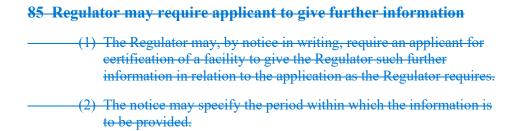
Part 7 Certification and accreditationDivision 2 Certification

Section 83



Certification and accreditation Part 7
Certification Division 2

Section 85



86 Conditions of certification

- (1) The certification of a facility is subject to the following conditions:
 - (a) any conditions imposed by the Regulator at the time of certification;
 - (b) any conditions imposed by the Regulator under section 87 or 87A after certification;
 - (c) any conditions specified in the rules prescribed by the regulations.
- (2) It is also a condition of the certification of a facility that the holder of the certification must permit an authorised inspector to enter, at a reasonable time, the facility for one or more of the following purposes:
 - (a) determining whether a provision subject to monitoring under Part 10 has been, or is being, complied with;
 - (b) determining whether information subject to monitoring under Part 10 is correct.
 - (3) Subsection (2) does not limit the conditions that may be:
 - (a) imposed by the Regulator at the time of certification; or
 - (b) imposed by the Regulator under section 87 or 87A after certification; or
 - (c) specified in the rules.

87 Variation of certification on Regulator's initiative

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

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Part 7 Certification and accreditationDivision 2 Certification

Section 87A

- (2) Without limiting subsection (1), the Regulator may:
 - (a) impose additional conditions; or
 - (b) remove or vary conditions that were imposed by the Regulator.

87A Variation of certification on application by holder

- (1) The holder of the certification of a facility may apply to the Regulator to vary the certification.
 - Note: Division 1A of Part 12 sets out requirements for applications.
 - (2) If the Regulator receives an application under subsection (1) to vary the certification of a facility, the Regulator must, within the consideration period for the application, decide:
 - (a) to vary the certification; or
 - (b) to refuse to vary the certification.
 - Note 1: See section 178F for the consideration period for the application.
 - Note 2: A decision to vary, or refuse to vary, a certification is a reviewable decision (see section 179), and the Regulator must give the applicant written notice of the decision (see section 180).

88 Suspension or cancellation of certification

- (1) 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 or the Regulator is no longer satisfied of a matter the Regulator was required to be satisfied of under section 84 at the time of certification.
- (2) The Regulator may, by notice in writing, suspend the certification of a facility if the holder of the certification requests the Regulator, in writing, to do so.

Certification and accreditation Part 7
Certification Division 2

Section 89

89 Regulator to notify of proposed suspension, cancellation or variation

- (1) Before varying a certification under section 87, or suspending or cancelling a certification under section 88Before suspending, cancelling or varying a certification under this Division, the Regulator must give written notice of the proposed suspension, cancellation or variation to the holder of the certification.
- (2) The notice:
 - (a) must state that the Regulator proposes to suspend, cancel or vary the certification; and
 - (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
 - (c) <u>mustmay</u> invite the holder of the certification to make a written submission to the Regulator about the proposed suspension, cancellation or variation.
- (3) The notice must specify a period within which the holder of the certification:
 - (a) must give the information referred to in paragraph (2)(b); and
 - (b) may make a submission under paragraph (2)(c). The period specified must be not less than 20 business days starting on the day after the day the notice is given. The period must not end earlier than 30 days after the day on which the notice was given.
- (4) In considering whether to suspend, cancel or vary a certification, the Regulator must have regard to any submission made under paragraph (2)(c).
- (5) This section does not apply to a suspension, cancellation or variation requested by the holder of the certification.
- (6) This section does not apply to a suspension, cancellation or variation of a certification if the Regulator considers that the suspension, cancellation or variation is necessary in order to avoid

Gene Technology Act 2000

Part 7 Certification and accreditation

Division 2 Certification

Section 89AA

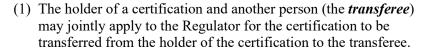
a significant risk to human health and safety or to the environmentan imminent risk of death, serious illness, serious injury or serious damage to the environment.

(7) This section does not apply to a variation of a certification if the Regulator is satisfied that the variation is of minor significance—or complexity.

89AA Surrender of certification

The holder of a certification of a facility may, with the consent of the Regulator, surrender the certification.

89A Transfer of certification



Note: Division 1A of Part 12 sets out requirements for applications.

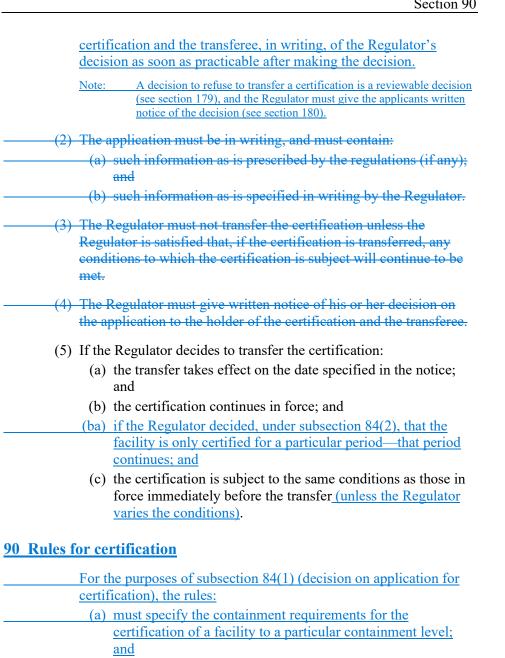
- (2) If the Regulator receives an application under subsection (1) to transfer the certification, the Regulator must, within the consideration period for the application, decide:
 - (a) to transfer the certification; or
 - (b) to refuse to transfer the certification.

Note: See section 178F for the consideration period for the application.

- (3) The Regulator must not transfer the certification if the Regulator is not satisfied of a matter, in relation to the transferee, that the Regulator was required to be satisfied of under section 84 at the time of certification.
- (4) However, the Regulator may make minor variations to any conditions to which the certification is subject in order to facilitate the transfer of the certification.
- (4A) If the Regulator decides to transfer the certification under subsection (2), the Regulator must notify the holder of the

Certification and accreditation Part 7 Certification Division 2

Section 90



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Part 7 Certification and accreditationDivision 2 Certification



(b) may specify other criteria the facility or applicant must comply with for the certification of the facility to a particular containment level.

90 Guidelines

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

Certification and accreditation Part 7
Accredited organisations Division 3

Section 91

Division 3—Accredited organisations

91 Application for accreditation

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

Note: Division 1A of Part 12 sets out requirements for applications.

Note 1: The conditions of a licence may require supervision of dealings by an Institutional Biosafety Committee established by an accredited organisation (see paragraph 62(2)(m)), and the regulations may require such supervision of notifiable low risk dealings (see paragraph 75(2)(c)).

Note 2: The conditions to which an emergency dealing determination is subject may require supervision of dealings by an Institutional Biosafety Committee established by an accredited organisation (see paragraph 72D(2)(t)).

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

92 Decision on application for accreditation

- (1) If a person applies for accreditation of an organisation, the

 Regulator must, within the consideration period for the application, decide:
 - (a) to accredit the organisation; or
 - (b) to refuse to accredit the organisation.

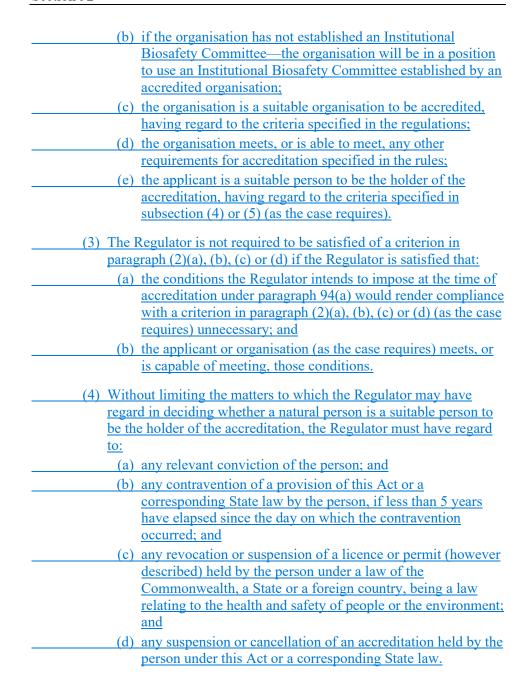
Note: See section 178F for the consideration period for the application.

- (2) Subject to subsection (3), the Regulator must not accredit an organisation under subsection (1) unless the Regulator is satisfied of the following:
 - (a) if the organisation has established an Institutional Biosafety Committee:
 - (i) the organisation will be able to maintain the Committee in accordance with the rules; and
 - (ii) the organisation has appropriate indemnity arrangements for its Committee members;

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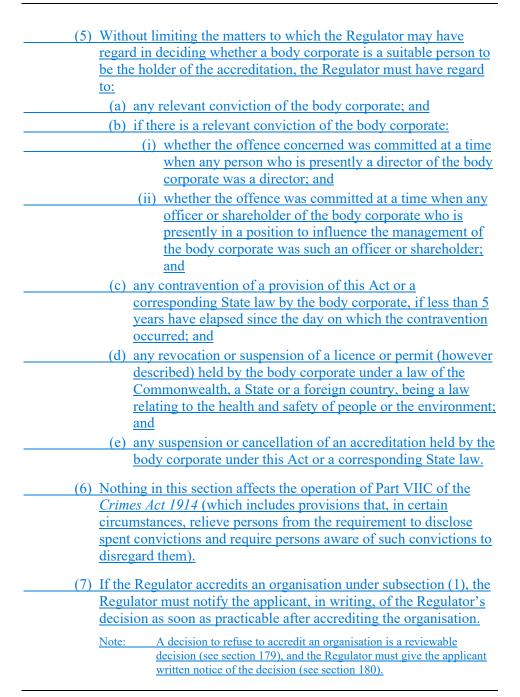
Part 7 Certification and accreditationDivision 3 Accredited organisations

Section 92



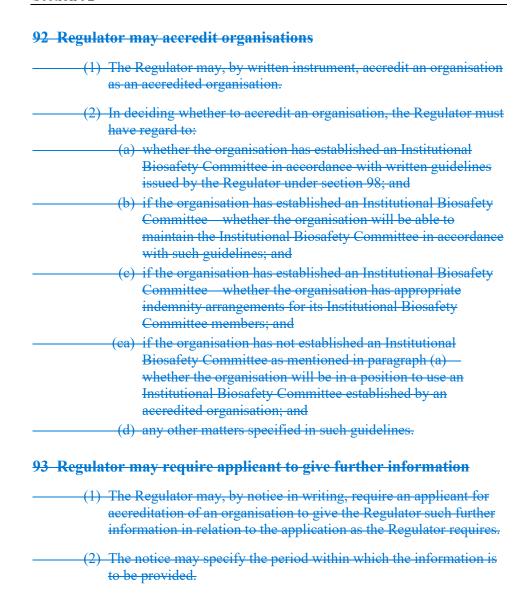
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Accredited organisations Division 3

Section 92



Part 7 Certification and accreditationDivision 3 Accredited organisations

Section 92



94 Conditions of accreditation

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

Certification and accreditation Part 7
Accredited organisations Division 3

Section 95

- (a) any conditions imposed by the Regulator at the time of accreditation;
- (b) any conditions imposed by the Regulator under section 95 or 95A after accreditation;
- (c) any conditions specified in the rulesprescribed by the regulations.

95 Variation of accreditation on Regulator's initiative

- (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.

95A Variation of accreditation on application by holder

- (1) The holder of the accreditation of an organisation may apply to the Regulator to vary the accreditation.
 - Note: Division 1A of Part 12 sets out requirements for applications.
- (2) If the Regulator receives an application under subsection (1) to vary the accreditation of an organisation, the Regulator must, within the consideration period for the application, decide:
 - (a) to vary the accreditation; or
 - (b) to refuse to vary the accreditation.
 - Note 1: See section 178F for the consideration period for the application.
 - Note 2: A decision to vary, or refuse to vary, an accreditation is a reviewable decision (see section 179), and the Regulator must give the applicant written notice of the decision (see section 180).

96 Suspension or cancellation of accreditation

The Regulator may, by notice in writing, suspend or cancel the accreditation of an organisation if the Regulator believes on

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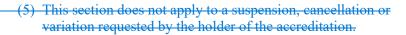
reasonable grounds that a condition of the accreditation has been breached or the Regulator is no longer satisfied of a criterion the Regulator was required to be satisfied of under section 92 at the time of accreditation.

97 Regulator to notify of proposed suspension, cancellation or variation

- (1) Before varying an accreditation under section 95, or suspending or cancelling an accreditation under section 96, Before suspending, cancelling or varying an accreditation under this Division, the Regulator must give written notice of the proposed suspension, cancellation or variation to the holder of the accreditation.
- (2) The notice:
 - (a) must state that the Regulator proposes to suspend, cancel or vary the accreditation; and
 - (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
 - (c) <u>mustmay</u> invite the holder of the accreditation to make a written submission to the Regulator about the proposed suspension, cancellation or variation.
- (3) The notice must specify a period within which the holder of the accreditation:
 - (a) must give the information referred to in paragraph (2)(b); and
 - (b) may make a submission under paragraph (2)(c).
 - The period specified must be not less than 20 business days starting on the day after the day the notice is given. The period must not end earlier than 30 days after the day on which the notice was given.
- (4) In considering whether to suspend, cancel or vary an accreditation, the Regulator must have regard to any submission made under paragraph (2)(c).

Certification and accreditation Part 7
Accredited organisations Division 3

Section 97A



- (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 a significant risk to human health and safety or to the environmentan imminent risk of death, serious illness, serious injury or serious damage to the environment.
- (7) This section does not apply to a variation of an accreditation if the Regulator is satisfied that the variation is of minor significance or complexity.

97A Surrender of accreditation

The holder of an accreditation of an organisation may, with the consent of the Regulator, surrender the accreditation.

98 Rules for Institutional Biosafety Committees and accreditation

For the purposes of subsection 92(2), the rules:

- (a) must specify requirements concerning the establishment and maintenance of Institutional Biosafety Committees; and
- (b) may specify any other requirement an organisation must meet, or be able to meet, for the accreditation of the organisation as an accredited organisation.

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.

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

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

Simplified outline Division 1

Section 99

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

Division 1—Simplified outline

99 Simplified outline

The following is a simplified outline of this Part:

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

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

Part 8 The Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee Division 2 The Gene Technology Technical Advisory Committee

Section 100

Division 2—The Gene Technology Technical Advisory Committee

100 The Gene Technology Technical Advisory Committee

- (1) The Gene Technology Technical Advisory Committee is established.
- (2) The Minister is to appoint up to 20 members of the Committee, and must appoint one of the members to chair the Committee.
- (3) The members hold office on a part-time basis.
- (4) Before appointing a member of the Committee, the Minister must consult: (a) the States; and (b) the Regulator. (4) Before appointing a member of the Committee, the Minister must consult the following: (a) the States;
 - (b) the Regulator;
 - (c) such scientific, consumer, health, environmental and industry groups as the Minister considers appropriate;
 - (d) such other Ministers as the Minister considers appropriate.
 - (5) Subject to subsections (6) and (7A), the Minister must not appoint a person as a member of the Committee unless the Minister is satisfied that the person has skills or experience in one or more of the following areas:
 - (a) molecular biology;
 - (b) ecology;
 - (c) plant, microbial, animal or human genetics;
 - (d) virology;
 - (e) entomology;
 - (f) agricultural or aquacultural systems;
 - (g) biosafety engineering;

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

The Gene Technology Technical Advisory Committee Division 2

Section 100

- (h) public health;
- (i) occupational health and safety;
- (j) risk assessment;
- (k) clinical medicine;
- (l) biochemistry;
- (m) pharmacology;
- (n) plant or animal pathology;
- (o) botany;
- (p) microbiology;
- (q) animal biology;
- (r) immunology;
- (s) toxicology;
- (t) an area specified by the regulations for the purposes of this paragraph.
- (6) The Minister must appoint a layperson as a member of the Committee. The Minister is not required to be satisfied that the person has skills or experience in an area mentioned in subsection (5).
- (7) In appointing the members of the Committee, the Minister must ensure, as far as practicable, that among the members as a whole there is a broad range of skills and experience in the areas mentioned in subsection (5).
- (7A) The Minister must ensure that the Committee includes at least one person who is a member of the Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee. The Minister is not required to be satisfied that this person has skills or experience in an area mentioned in subsection (5).
 - (8) The Minister must not appoint a member to chair the Committee unless a majority of jurisdictions agree to the appointment.

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Part 8 The Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee
Division 2 The Gene Technology Technical Advisory Committee

Section 101

101 Function of the Gene Technology Technical Advisory Committee

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

- (a) gene technology, GMOs and GM products;
- (b) applications made under this Act;
- (c) the biosafety aspects of gene technology;
- (d) legislative instruments and proposed legislative instruments made by the Regulator under this Act;
- (e) the need for policy principles, policy guidelines, and technical and procedural guidance in relation to GMOs, and the content of such principles and guidance.
- (d) the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products, and the content of such principles, guidelines and codes.

102 Expert advisers

- (1) The Minister may appoint one or more persons (*expert advisers*) to give expert advice to the Gene Technology Technical Advisory Committee to assist it in the performance of its functions. Expert advisers may be appointed on a continuing or an ad hoc basis.
- (2) For the avoidance of doubt, expert advisers are not Committee members.

103 Remuneration

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

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

The Gene Technology Technical Advisory Committee Division 2

Section 104

- operation, the member is to be paid the remuneration that is prescribed by the regulations.
- (2) A person who is a member of the Gene Technology Technical Advisory Committee or an expert adviser is to be paid the allowances that are prescribed by the regulations.
- (3) This section has effect subject to the *Remuneration Tribunal Act* 1973.

104 Members and procedures

- (1) The regulations may prescribe matters relating to the members of the Gene Technology Technical Advisory Committee and expert advisers, including, but not limited to, the following:
 - (a) term of appointment;
 - (b) resignation;
 - (c) disclosure of interests;
 - (d) termination of appointment;
 - (e) leave of absence.
- (2) The regulations may prescribe matters relating to the operation of the Gene Technology Technical Advisory Committee, including, but not limited to:
 - (a) procedures for convening meetings of the Committee; and
 - (b) the constitution of a quorum for a meeting of the Committee; and
 - (c) the way in which matters are to be resolved by the Committee; and
 - (d) Committee records; and
 - (e) reporting requirements, including, but not limited to, reports to the Regulator and to the public.
- (3) If no regulations are in force under subsection (2), the Committee must operate in the way determined by the Regulator in writing.

Gene Technology Act 2000

Part 8 The Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee
Division 2 The Gene Technology Technical Advisory Committee

Section 105

- (4) If no regulations are in force under subsection (2) and no determination is in force under subsection (3), the Committee may operate in the way it determines.
- (5) A determination made under subsection (3) is not a legislative instrument.

105 Subcommittees

- (1) The Gene Technology Technical Advisory Committee may, with the Regulator's consent, establish subcommittees to assist in the performance of its functions.
- (2) The regulations may prescribe matters relating to the constitution and operation of subcommittees.

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

The Gene Technology Ethics and Community Consultative Committee Division 3

Section 106

Division 3—The Gene Technology Ethics and Community Consultative Committee

106 The Gene Technology Ethics and Community Consultative Committee

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

107 Function of Gene Technology Ethics and Community <u>Consultative Committee</u> Ethics and Community <u>Committee</u>

The function of the Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee is to provide advice, on the request of the Regulator or the Ministerial Council, on the following:

- (a) ethical issues relating to gene technology;
- (b) the need for, and content of, codes of practice in relation to ethics in respect of conducting dealings with GMOs;
- (c) the need for, and content of, policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons;
- (d) the need for policy principles, policy guidelines and technical and procedural guidance in relation to GMOs and the content of such principles and guidance;
- (e) risk communication, consultation and engagement with the community by the Regulator in relation to GMOs;
- (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;
- (e) community consultation in respect of the process for applications for licences covering dealings that involve the intentional release of a GMO into the environment;

Gene Technology Act 2000

Part 8 The Gene Technology Technical Advisory Committee and the Gene
Technology Ethics and Community Consultative Committee
Division 3 The Gene Technology Ethics and Community Consultative Committee

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- (f) risk communication matters in relation to dealings that involve the intentional release of a GMO into the environment:
- (g) matters of general concern identified by the Regulator in relation to applications made under this Act;
- (h) matters of general concern in relation to GMOs.

108 Membership

- (1) The Minister is to appoint up to 12 members of the <u>Gene</u>
 <u>Technology Ethics and Community Consultative Committee Ethics</u>
 <u>and Community Committee</u>, and must appoint one of the members to chair the <u>Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee</u>.
- (2) Before appointing a member of the Gene Technology Ethics and Community Consultative Committee (other than a member mentioned in paragraph (4)(b)), the Minister must consult:
 - (a) the States; and
 - (b) the Regulator.
 - (2A) For a member of the Gene Technology Ethics and Community

 Consultative Committee mentioned in paragraph (4)(b), the

 Minister must:
 - (a) before appointing the member, consult the Regulator; and
 - (b) after appointing the member, inform the States of the appointment.
- (2) Before appointing a member of the Ethics and Community Committee, the Minister must consult the following:
 - (a) the States;
 - (b) the Regulator;
 - (c) such scientific, consumer, health, environmental and industry groups as the Minister considers appropriate;
 - (d) such other Ministers as the Minister considers appropriate.

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

The Gene Technology Ethics and Community Consultative Committee Division 3

Section 108

- (3) The Minister must not appoint a person as a member of the Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee (other than as a member mentioned in subsection (4)) unless the Minister is satisfied that the person has skills or experience of relevance to gene technology in relation to one or more of the following:
 - (a) community consultation;
 - (b) risk communication;
 - (c) the impact of gene technology on the community;
 - (d) issues relevant to businesses developing or using biotechnology;
 - (e) issues relevant to gene technology research;
 - (f) issues relevant to local government;
 - (g) issues of concern to consumers;
 - (h) law;
 - (i) religious practices;
 - (j) human health;
 - (k) animal health and welfare;
 - (1) primary production;
 - (m) ethics;
 - (n) environmental issues;
 - (o) issues specified by the regulations for the purposes of this paragraph.
- (4) The Minister must ensure that the Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee includes the following members:
 - (a) a person who is a member of the Gene Technology Technical Advisory Committee;
 - (b) a person who is a member of the Australian Health Ethics Committee.
- (5) The members of the <u>Gene Technology Ethics and Community</u>
 <u>Consultative Committee Ethics and Community Committee</u> hold office on a part-time basis.

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Section 109

(6) The Minister must not appoint a member to chair the <u>Gene</u>
<u>Technology Ethics and Community Consultative Committee Ethics</u>
<u>and Community Committee</u> unless a majority of jurisdictions agree to the appointment.

109 Remuneration

- (1) A person who is a member of the <u>Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee</u> or an expert adviser is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination of that remuneration by the Tribunal is in operation, the member is to be paid the remuneration that is prescribed by the regulations.
- (2) A person who is a member of the Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee or an expert adviser is to be paid the allowances that are prescribed by the regulations.
- (3) This section has effect subject to the *Remuneration Tribunal Act* 1973.

110 Membership and Procedures

- (1) The regulations may prescribe matters relating to the members of the <u>Gene Technology Ethics and Community Consultative</u>
 <u>Committee Ethics and Community Committee</u>, including, but not limited to, the following:
 - (a) term of appointment;
 - (b) resignation;
 - (c) disclosure of interests;
 - (d) termination of appointment;
 - (e) leave of absence.
- (2) The regulations may prescribe matters relating to the operation of the <u>Gene Technology Ethics and Community Consultative</u>
 <u>Committee Ethics and Community Committee</u>, including, but not limited to, the following:

The Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee Part 8
The Gene Technology Ethics and Community Consultative Committee Division 3

Section 111

- (a) procedures for convening meetings of the <u>Gene Technology</u>
 <u>Ethics and Community Consultative Committee</u> <u>Ethics and Community Committee</u>;
- (b) the constitution of a quorum for a meeting of the Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee;
- (c) the way in which matters are to be resolved by the <u>Gene Technology Ethics and Community Consultative</u>
 Committee <u>Ethics and Community Committee</u>;
- (d) Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee records;
- (e) reporting requirements, including, but not limited to, reports to the Regulator and to the public.
- (3) If no regulations are in force under subsection (2), the Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee must operate in the way determined in writing by the Regulator.
- (4) If no regulations are in force under subsection (2) and no determination is in force under subsection (3), the <u>Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee</u> may operate in the way determined in writing by the <u>Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee</u>.
- (5) A determination made under subsection (3) or (4) is not a legislative instrument.

111 Subcommittees

- (1) The <u>Gene Technology Ethics and Community Consultative</u>
 <u>Committee Ethics and Community Committee</u> may, with the Regulator's consent, establish subcommittees to assist in the performance of its functions.
- (2) The regulations may prescribe matters relating to the constitution and operation of subcommittees.

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Part 8 The Gene Technology Technical Advisory Committee and the Gene
Technology Ethics and Community Consultative Committee
Division 3 The Gene Technology Ethics and Community Consultative Committee

Section 112

112 Expert advisers

- (1) The Minister may appoint one or more persons (*expert advisers*) to give expert advice to the <u>Gene Technology Ethics and Community Consultative Committee Ethics and Community Committee</u> to assist it in the performance of its functions. Expert advisers may be appointed on a continuing or an ad hoc basis.
- (2) Expert advisers are not members of the <u>Gene Technology Ethics</u> and <u>Community Consultative Committee</u> <u>Ethics and Community Committee</u>.

Administration Part 9
Simplified outline Division 1

Section 117

Part 9—Administration

Division 1—Simplified outline

117 Simplified outline

The following is a simplified outline of this Part:

This Part provides for various administrative matters.

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

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

Division 4 provides for matters relating to staffing.

Division 5 sets out reporting requirements.

Division 6 requires the Regulator to maintain a record of GMO dealings.

Division 7 provides for the appointment of authorised inspectors.

Division 8 deals with powers conferred on issuing officers.

<u>Division 9 allows an authorised inspector to be assisted by other persons in particular circumstances.</u>

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

Gene Technology Act 2000

Part 9 Administration

Division 2 Appointment and conditions of Regulator

Section 118

Division 2—Appointment and conditions of Regulator

118 Appointment of the Regulator

- (1) The Regulator is to be appointed by the Governor-General by written instrument.
- (2) The Regulator holds office for the period specified in the instrument of appointment. The period specified must not be less than 3 years or more than 5 years.
- (3) The Regulator holds office on a full-time basis.
- (4) The Governor-General must not appoint a person as the Regulator unless a majority of jurisdictions agree to the appointment.
- (5) The Governor-General must not appoint a person as the Regulator if, at any time during the period of 2 years immediately before the proposed period of appointment, the person was employed by a body corporate whose primary commercial activity relates directly to the development and implementation of gene technologies.
- (6) The Governor-General must not appoint a person as the Regulator if the person has a pecuniary interest in a body corporate whose primary commercial activity relates directly to the development and implementation of gene technologies.

119 Termination of appointment

- (1) The Governor-General may terminate the appointment of the Regulator for misbehaviour or physical or mental incapacity.
- (2) If the Regulator:
 - (a) becomes bankrupt, applies to take the benefit of any law for the relief of bankrupt or insolvent debtors, compounds with his or her creditors or makes an assignment of his or her remuneration for their benefit; or
 - (b) fails to comply with his or her obligations under section 120; or

Administration Part 9
Appointment and conditions of Regulator Division 2

Section 119

- (c) without the consent of the Minister, engages in any paid employment outside the duties of his or her office; or
- (d) is absent from duty, except on leave of absence, for 14 consecutive days or for 28 days in any 12 months; the Governor-General must terminate his or her appointment.
- (3) The Governor-General must not terminate the appointment of the Regulator under subsection (1) unless a majority of jurisdictions agree to the termination of the appointment.
- (4) If the Regulator is:
 - (a) an eligible employee for the purposes of the *Superannuation Act 1976*; or
 - (b) a member of the superannuation scheme established by deed under the *Superannuation Act 1990*; or
 - (c) an ordinary employer-sponsored member of PSSAP, within the meaning of the *Superannuation Act 2005*;
 - the Governor-General may, with the consent of the Regulator, retire the Regulator from office on the grounds of physical or mental incapacity.
- (5) For the purposes of the *Superannuation Act 1976*, the Regulator is taken to have been retired from office on the grounds of invalidity if:
 - (a) the Regulator is removed or retired from office on the grounds of physical or mental incapacity; and
 - (b) CSC gives a certificate under section 54C of that Act.
- (6) For the purposes of the *Superannuation Act 1990*, the Regulator is taken to have been retired from office on the grounds of invalidity if:
 - (a) the Regulator is removed or retired from office on the grounds of physical or mental incapacity; and
 - (b) CSC gives a certificate under section 13 of that Act.
- (7) For the purposes of the *Superannuation Act 2005*, the Regulator is taken to have been retired from office on the grounds of invalidity if:

Gene Technology Act 2000

Part 9 Administration

Division 2 Appointment and conditions of Regulator

Section 120

- (a) the Regulator is removed or retired from office on the grounds of physical or mental incapacity; and
- (b) CSC gives an approval and certificate under section 43 of that Act.

120 Disclosure of interests

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

121 Acting appointment

The Minister may appoint a person to act as the Regulator:

- (a) during a vacancy in the office of Regulator, (whether or not an appointment has previously been made to the office); or
- (b) during any period, or during all periods, when the Regulator is absent from duty or from Australia, or is, for any reason, unable to perform the duties of the office.

Note: For rules that apply to acting appointments, see section 33A of the *Acts Interpretation Act 1901*.

122 Terms and conditions

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

123 Outside employment

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

Administration Part 9
Appointment and conditions of Regulator Division 2

Section 124

124 Remuneration

- (1) The Regulator is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination of that remuneration by the Tribunal is in operation, the Regulator is to be paid the remuneration that is prescribed by the regulations.
- (2) The Regulator is to be paid the allowances that are prescribed by the regulations.
- (3) This section has effect subject to the *Remuneration Tribunal Act* 1973.

125 Leave of absence

- (1) The Regulator has the recreation leave entitlements that are determined by the Remuneration Tribunal.
- (2) The Minister may grant the Regulator leave of absence, other than recreation leave, on the terms and conditions as to remuneration or otherwise that the Minister determines.

126 Resignation

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

Gene Technology Act 2000

Part 9 Administration Division 3 Money

Section 127

Division 3—Money

127 Regulator may charge for services

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

128 Notional payments by the Commonwealth

- (1) The purpose of this section is to ensure that fees and charges under this Act and the regulations, and charges under the *Gene Technology (Licence Charges) Act 2000*, are notionally payable by the Commonwealth (or parts of the Commonwealth).
- (2) The Minister responsible for administering the *Public Governance*, *Performance and Accountability Act 2013* may give written directions for the purpose of this section, including directions relating to the transfer of amounts within, or between, accounts operated by the Commonwealth.

129 Gene Technology Account

- (1) The Gene Technology Account is established.
- (2) The Account is a special account for the purposes of the *Public Governance, Performance and Accountability Act 2013*.

130 Credits to Account

- (1) There must be credited to the Account the following:
 - (b) amounts equal to money from time to time received by the Commonwealth under the *Gene Technology (Licence Charges) Act 2000*;
 - (c) amounts equal to fees received by the Commonwealth under paragraph 75(2)(e), 75C(2)(e) or 178B(1)(d)subsections 40(6) and 83(3);

Administration Part 9
Money Division 3

Section 131

- (d) amounts equal to amounts received by the Commonwealth in connection with the performance of the Regulator's functions under this Act, the regulations or a corresponding State law;
- (e) amounts equal to interest received by the Commonwealth from the investment of amounts standing to the credit of the Account;
- (f) amounts equal to money received by the Commonwealth in relation to property paid for with amounts standing to the credit of the Account;
- (g) amounts equal to amounts recovered by the Commonwealth under <u>subsection 161A(4) or 167(8)</u> subsection 146(5) or 158(4), to the extent that they are referable to amounts debited from the Account;
- (h) amounts equal to amounts of any gifts given or bequests made for the purposes of the Account.

Note: An Appropriation Act provides for amounts to be credited to a special account if any of the purposes of the special account is a purpose that is covered by an item in the Appropriation Act.

- (2) The purposes of the Account are to make payments:
 - (a) to further the object of this Act (as set out in section 3); and
 - (b) otherwise in connection with the performance of the Regulator's functions under this Act, the regulations or a corresponding State law.

131 Recovery, waiver and refund of amounts

- (1) The following amounts may be recovered in a court of competent jurisdiction as debts due to the Commonwealth:
 - (a) amounts payable to the Commonwealth under the *Gene Technology (Licence Charges) Act 2000*;
 - (b) fees payable to the Commonwealth under this Act, the regulations or a corresponding State law;
 - (c) amounts payable to the Commonwealth in connection with the performance of the Regulator's functions.

Gene Technology Act 2000

Part 9 Administration Division 3 Money

Section 132

- (2) The Regulator may wholly or partly waive, or wholly or partly refund, the following amounts, in the circumstances prescribed by the regulations:
 - (a) fees that would otherwise be payable to the Commonwealth under this Act, the regulations, or a corresponding State law;
 - (b) amounts that would otherwise be payable to the

 Commonwealth in connection with the performance of the Regulator's functions.

132 Purposes of Account

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

- (a) in payment or discharge of the costs, expenses and other obligations incurred:
 - (i) by the Regulator in the performance of the Regulator's functions or in the exercise of the Regulator's powers under this Act, the regulations or a corresponding State law; or
 - (ii) by an <u>authorised inspector under paragraph</u>

 161A(2)(e)inspector under paragraph 158(2)(e) or under a corresponding State law; and
- (b) in payment of any remuneration and allowances payable to any person under this Act or the regulations; and-
- (c) in making any other payments which the Regulator is authorised or required to make under this Act or the regulations.

Administration Part 9
Staffing Division 4

Section 133

Division 4—Staffing

133 Staff assisting the Regulator

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

134 Consultants

- (1) The Regulator may engage persons with suitable qualifications and experience as consultants to the Regulator.
- (2) The terms and conditions of engagement of consultants are such as the Regulator determines.

135 Seconded officers

The Regulator may be assisted by the following:

- (a) persons engaged under the Public Service Act 1999;
- (b) officers and employees of Commonwealth authorities;
- (c) officers and employees of State agencies;

whose services are made available to the Regulator in connection with the performance or exercise of any of the Regulator's functions or powers.

Gene Technology Act 2000

Division 5—Reporting requirements

136 Annual Report

- (1) As soon as practicable after the end of each financial year, the Regulator must prepare and give to the Minister a report on the operations of the Regulator during that year.
- (1A) The report must include information about the following:
 - (a) GMO licences <u>and GMO permits</u> issued during the financial year;
 - (b) any breaches of conditions of a GMO licence, or a GMO permit, that have come to the Regulator's attention during the financial year;
 - (c) emergency dealing determinations made by the Minister during the financial year;
 - (d) any breaches of conditions of an emergency dealing determination that have come to the Regulator's attention during the financial year;
 - (e) monitoring, compliance and enforcement activities undertaken during the financial year.
 - (e) auditing and monitoring of dealings with GMOs under this Act by the Regulator or an inspector during the financial year.

Note: <u>Monitoring Auditing and monitoring</u> may include spot checks.

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

137 Reports to Parliament

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

Administration Part 9
Reporting requirements Division 5

Section 137

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

Gene Technology Act 2000

Division 6—Record of GMO Dealings

138 Record of GMO Dealings

- (1) The Regulator must maintain a Record of GMO Dealings (the *Record*).
 - Note: A person may request access to the Record under the *Freedom of Information Act 1982*.
- (2) The purpose of the Record is to maintain a comprehensive record of <u>certainall</u> dealings in Australia that involve GMOs.
- (3) The Record must contain the following information in relation to each GMO licence, 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 with GMOs authorised by the licence and the GMOs to which those dealings relate;
 - (c) the dealings authorised by the licence and the GMO to which those dealings relate;
 - (d) any licence conditions imposed under paragraph 61(c) or (d);
 - (e) the date on which the licence was issued, and its expiry date (if any).
- (3AA) The Record must contain the following information in relation to each GMO permit issued under section 72AD:
 - (a) the name of the permit holder;
 - (b) the persons covered by the permit;
 - (c) the permit dealings authorised by the permit;
 - (d) the date on which the permit was issued, and its expiry date (if any).
 - (3A) The Record must contain the following information, other than confidential commercial information, in relation to each emergency dealing determination made under section 72B:

Administration Part 9
Record of GMO Dealings Division 6

Section 138

- (a) the dealings specified in the emergency dealing determination and the GMO to which those dealings relate;
- (b) any conditions to which the emergency dealing determination is subject;
- (c) the date on which the emergency dealing determination takes effect:
- (d) the date on which the emergency dealing determination will cease to have effect.
- (4) The Record must contain the following information in relation to each notifiable dealing that is notified to the Regulator:
 - (a) the name of the person who notified the notifiable dealing;
 - (b) any particulars of the notifiable dealing prescribed by the regulations.
- (4) The Record must contain the following information, other than confidential commercial information, in relation to each notifiable low risk dealing that is notified to the Regulator in accordance with regulations under section 75:
 - (a) the name of the person who notified the dealing;
 - (b) such particulars of the dealing as are prescribed by the regulations for the purposes of this paragraph.
- (6) The Record must also contain:
 - (a) a description of each dealing on the GMO Register; and
 - (b) any condition to which the dealing is subject.
- (7) The Record may be kept in a computerised form.
- (8) The Regulator must ensure that information mentioned in subsection (3), (3AA), (3A), (4) or (6) is entered on the Record as soon as reasonably practicable.
- (9) In this section:

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

Gene Technology Act 2000

Part 9 AdministrationDivision 6 Record of GMO Dealings

Section 139

130	Inspection	of Record
10)	Inspection	or record

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

Administration Part 9

Appointment of authorised inspectors and identity cards Division 7

Section 140

<u>Division 7—Appointment of authorised inspectors and</u> identity cards

140 Appointment of authorised inspectors

- (1) The Regulator may, in writing, appoint an APS employee who holds or performs the duties of an APS Level 6 position, or an equivalent or higher position, as an authorised inspector.
- (2) The Regulator must not appoint a person as an authorised inspector unless the Regulator is satisfied that the person has the knowledge or experience necessary to properly exercise the powers of an authorised inspector.
 - (3) In exercising powers or performing functions as an authorised inspector, an authorised inspector must comply with any directions of the Regulator.
 - (4) If a direction is given under subsection (3) in writing, the direction is not a legislative instrument.

141 Identity card

- (1) The Regulator must issue an identity card to an authorised inspector.
 - (2) The identity card:
 - (a) must be in the form prescribed by the regulations; and
 - (b) contain a photograph that is no more than 5 years old of the authorised inspector.
 - (3) A person commits an offence if:
 - (a) the person has been issued with an identity card; and
 - (b) the person ceases to be an authorised inspector; and
 - (c) the person does not return the identity card to the Regulator within 10 business days after ceasing to be an authorised inspector.

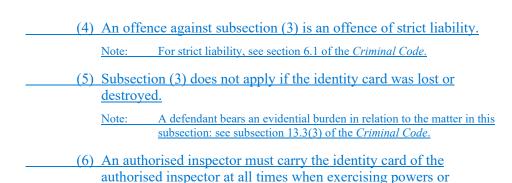
Penalty: 1 penalty unit.

Gene Technology Act 2000

Part 9 Administration

Division 7 Appointment of authorised inspectors and identity cards

Section 141



performing functions as an authorised inspector.

Administration Part 9
Issuing officers Division 8

Section 142

Division 8—Issuing officers

142 Powers conferred personally and protection and immunity

- (1) A power conferred on an issuing officer by Part 10 or 10A is conferred on the issuing officer:
 - (a) in a personal capacity; and
 - (b) not as a court or a member of a court.
 - Note: For the definition of *issuing officer*, see subsection 10(1).
 - (2) The issuing officer need not accept the power conferred.
- (3) An issuing officer exercising a power conferred by Part 10 or 10A

 has the same protection and immunity as if the issuing officer were exercising the power:
 - (a) as the court of which the issuing officer is a member; or
 - (b) as a member of the court of which the issuing officer is a member.

Part 9 AdministrationDivision 9 Persons assisting authorised inspectors

143 Persons assisting authorised inspectors

Section 143

Division 9—Persons assisting authorised inspectors

(1) An authorised inspector may be assisted by other persons in exercising powers or performing functions or duties under Part 10, 10A, 10B or 10C if:

- (a) the person is a person who, in the authorised inspector's opinion, has the skills, qualifications or experience necessary to assist the authorised inspector to exercise that power or perform that function; and
- (b) that assistance is necessary and reasonable.

A person giving such assistance is a *person assisting* the authorised inspector.

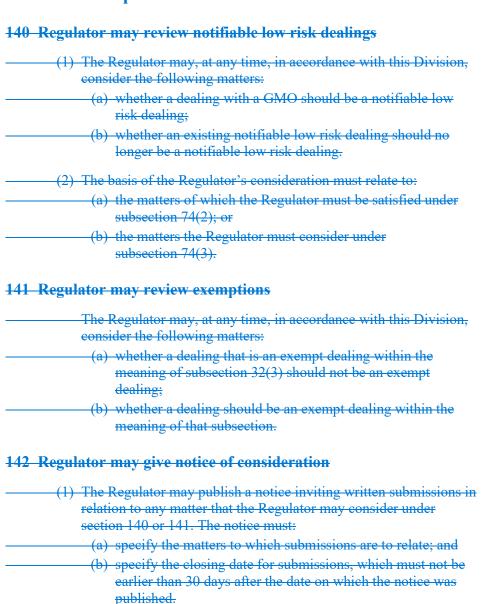
- (2) A person assisting the authorised inspector may enter premises if it is necessary for the authorised inspector to enter those premises for the purposes of exercising powers under Part 10, 10A, 10B or 10C.
- (3) For the purposes of assisting the authorised inspector, the person assisting may exercise the powers, or perform functions or duties, of the authorised inspector under those Parts, but only in accordance with directions given by the authorised inspector.
- (4) A power exercised, or a function or duty performed, by the person assisting in accordance with subsections (2) or (3) is taken for all purposes to have been exercised or performed by the authorised inspector.
 - (5) If a direction is given under subsection (3) in writing, the direction is not a legislative instrument.

Administration Part 9

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

Section 140

Division 7—Reviews of notifiable low risk dealings and exemptions



Gene Technology Act 2000

Part 9 Administration

Division 7 Reviews of notifiable low risk dealings and exemptions

Section 143 (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; and (b) the Gene Technology Technical Advisory Committee; 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. 143 What Regulator may do after consideration (1) If: (a) the matter relates to whether a dealing should be a notifiable low risk dealing; and (b) the Regulator is satisfied as mentioned in subsection 74(2); (c) the Regulator has considered the matters mentioned in subsection 74(3); the Regulator may recommend to the Ministerial Council that the dealing be declared to be a notifiable low risk dealing. (a) the matter relates to whether an existing notifiable low risk dealing be reconsidered; and (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: (a) should be an exempt dealing; or (b) should cease to be an exempt dealing;

Gene Technology Act 2000

the Regulator may recommend to the Ministerial Council that the

regulations be amended accordingly.

Administration **Part 9**Reviews of notifiable low risk dealings and exemptions **Division 7**

Section 144

144 Regulator not required to review matters

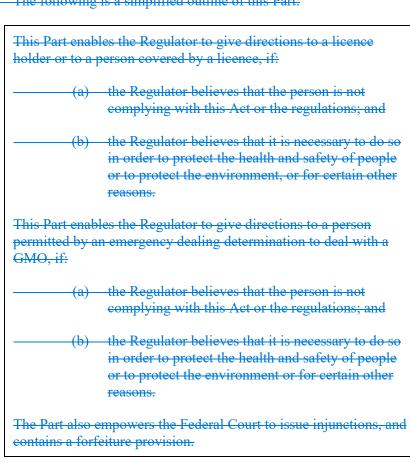
Nothing in this Division requires the Regulator to consider a matter under section 140 or 141.

Gene Technology Act 2000

Part 10 Enforcement

145 Simplified outline

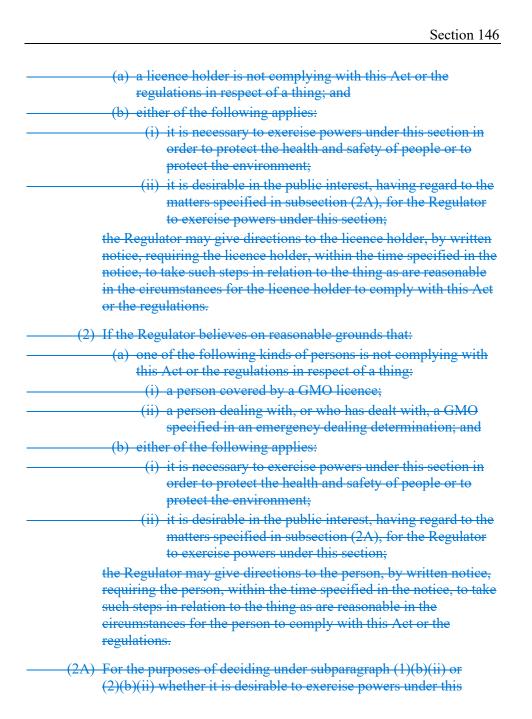
The following is a simplified outline of this Part:



146 Regulator may give directions

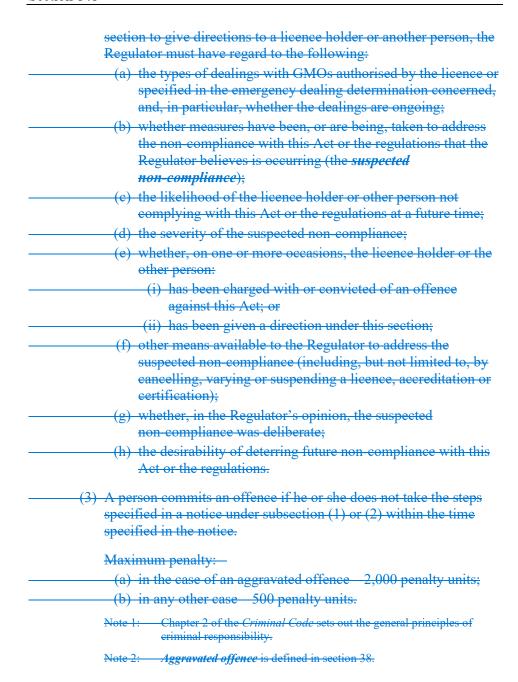
(1) If the Regulator believes, on reasonable grounds, that:

Enforcement Part 10



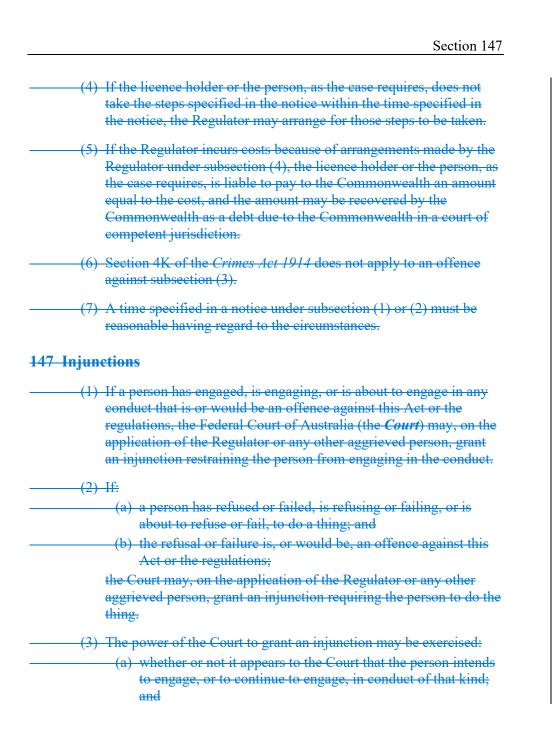
Gene Technology Act 2000

Section 146



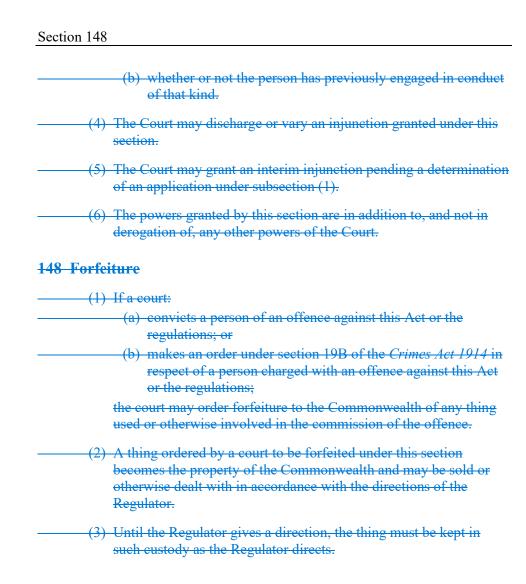
Gene Technology Act 2000

Enforcement Part 10



Gene Technology Act 2000

Part 10 Enforcement



Monitoring **Part 10**Outline and operation of this Part **Division 1**

Section 145

Part 10—Monitoring

Division 1—Outline and operation of this Part

145 Simplified outline

The following is a simplified outline of this Part:

This Part provides for the following:

- (a) monitoring whether provisions of this Act or a

 legislative instrument made under this Act have been, or
 are being, complied with;
- (b) monitoring whether information given in compliance, or purported compliance, with a provision of this Act or a legislative instrument made under this Act is correct.

An authorised inspector may, in certain circumstances, enter premises for the purpose of monitoring.

An authorised inspector who enters premises may exercise monitoring powers. The authorised inspector may be assisted by other persons if that assistance is necessary and reasonable.

145A Provisions and information subject to monitoring

- (1) A provision is *subject to monitoring* under this Part if it is:
 - (a) a provision of this Act; or
 - (b) a provision of a legislative instrument made under this Act; or
 - (c) an offence against the *Crimes Act 1914* or the *Criminal Code* that relates to this Act.
- (2) Information given in compliance, or purported compliance, with a provision of this Act or a legislative instrument made under this Act is *subject to monitoring* under this Part.

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Part 10 MonitoringDivision 2 Powers of authorised inspectors

Section 146

Division 2—Powers of authorised inspectors

Subdivision A—Monitoring powers

<u>146</u>	Entering	premises b	by consent of	or under a	a warrant etc.

(1) An authorised inspector may enter any premises and exercise the monitoring powers for one or more of the following purposes: (a) determining whether a provision subject to monitoring under this Part has been, or is being, complied with; (b) determining whether information subject to monitoring under this Part is correct. The monitoring powers are set out in sections 146A, 146B, 146C, Note: 146CA and 146D. (2) However, an authorised inspector is not authorised to enter the premises unless: (a) the occupier of the premises has consented to the entry; or (b) the entry is made under a monitoring warrant; or (c) all of the following apply: (i) the entry is at a reasonable time; (ii) the premises is a facility that is certified under Division 2 of Part 7; (iii) the occupier of the premises is the holder of the certification; or (d) the circumstance covered by subsection (3) applies. If entry to the premises is with the occupier's consent, the authorised Note: inspector must leave the premises if the consent ceases to have effect (see section 147). (3) A circumstance is covered by this subsection if all of the following apply: (a) the entry is at a reasonable time; (b) the occupier of the premises is a person dealing with, or who has dealt with, a GMO at the premises; (c) the dealing with the GMO is, or was:

Monitoring Part 10 Powers of authorised inspectors Division 2

Section 146A
(i) authorised by a GMO licence, and a condition under
paragraph 61(b), (c) or (d) applies or applied to the
person; or
(ii) authorised by a GMO permit, and a condition under
paragraph 72AE(1)(b) applies or applied to the person;
<u>or</u>
(iii) specified in an emergency dealing determination, and a
condition of the determination applies or applied to the
person.
146A General monitoring powers
140A General monitoring powers
The following are the <i>monitoring powers</i> that an authorised
inspector may exercise in relation to premises under section 146:
(a) the power to search the premises and any thing on the
premises;
(b) the power to examine or observe any activity conducted on
the premises;
(c) the power to inspect, examine, take measurements of or
conduct tests on any thing on the premises;
(d) the power to sample any thing on the premises;
(e) the power to inspect, examine, take measurements of,
conduct tests on or analyse such samples;
(f) the power to make any still or moving image or any
recording of the premises or any thing on the premises;
(g) the power to inspect any document on the premises;
(h) the power to take extracts from, or make copies of, any such
document;
(i) the power to take onto the premises such equipment and
materials required for the purpose of exercising powers in relation to the premises;
*
(j) if the occupier of the premises has consented to the entry or the entry is made under a monitoring warrant—the power to
remove samples from the premises, and inspect, examine,
take measurements of or conduct tests on such samples.

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Thing is defined in subsection 10(1).

Note:

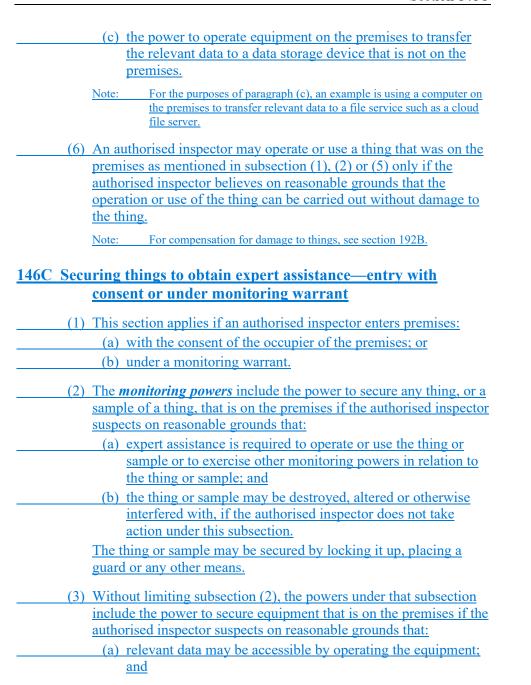
Part 10 MonitoringDivision 2 Powers of authorised inspectors

Section 146B

146B Operating and using things on premises (1) The *monitoring powers* include the power to operate or use a thing on the premises. (2) Without limiting subsection (1), the powers under that subsection include the power to: (a) operate equipment on the premises; and (b) use a data storage device that can be used with, or is associated with, the equipment. **Equipment** includes electronic equipment (see subsection 10(1)). Note 2: For the definition of *data storage device*, see subsection 10(1). (3) The *monitoring powers* include the powers mentioned in subsection (5) if relevant data is found in the exercise of the power under subsection (2). (4) **Relevant data** means information (whether or not held on the premises) that is relevant to determining: (a) whether a provision that is subject to monitoring under this Part has been, or is being, complied with; or (b) whether information subject to monitoring under this Part is correct. (5) If relevant data is found, the powers are as follows: (a) the power to operate equipment on the premises to put the relevant data in documentary form and remove the documents so produced from the premises; (b) the power to operate equipment on the premises to transfer the relevant data to a data storage device that: (i) is brought to the premises for the exercise of the power; or (ii) is on the premises and the use of which for that purpose has been agreed in writing by the occupier of the premises; and remove the data storage device from the premises;

Monitoring Part 10 Powers of authorised inspectors Division 2

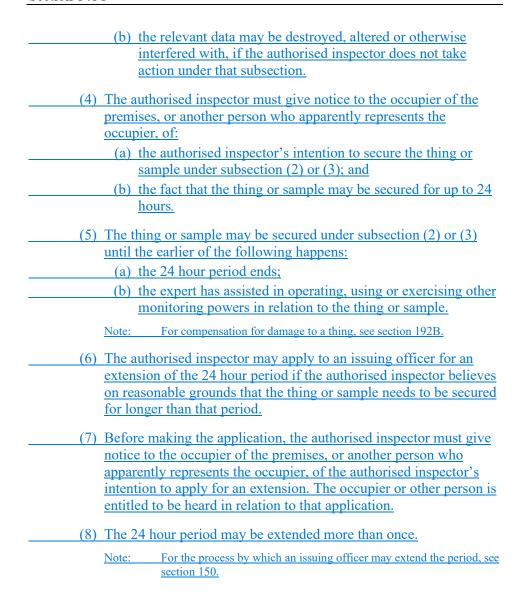
Section 146C



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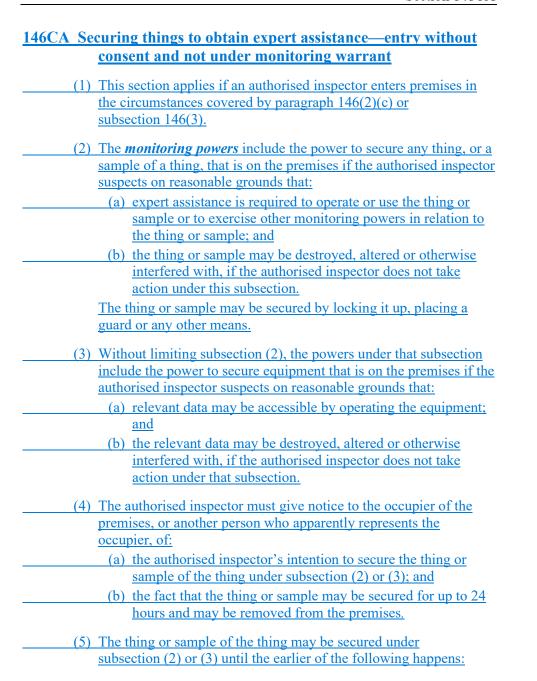
Part 10 MonitoringDivision 2 Powers of authorised inspectors

Section 146C



Monitoring Part 10 Powers of authorised inspectors Division 2

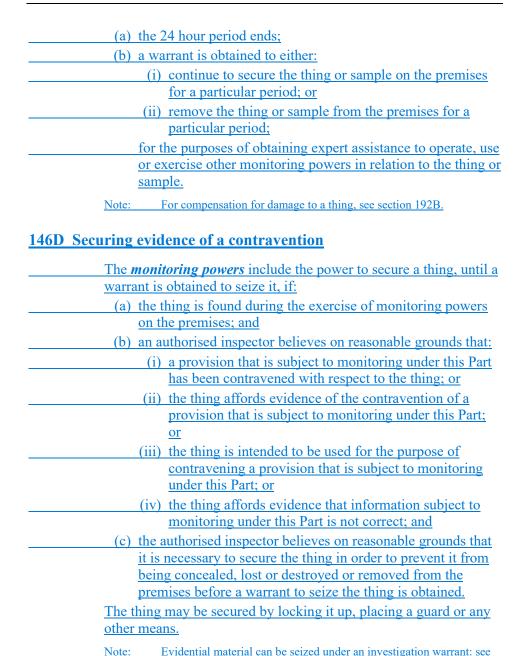
Section 146CA



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Part 10 MonitoringDivision 2 Powers of authorised inspectors

Section 146D



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Part 10A.

Monitoring Part 10 Powers of authorised inspectors Division 2

Section 146E

<u>Subdivision B—Powers to ask questions and seek production of</u> documents

146E Asking questions and seeking production of documents (1) This section applies if an authorised inspector enters premises for the purposes of determining: (a) whether a provision subject to monitoring under this Part has been, or is being, complied with; or (b) whether information subject to monitoring under this Part is correct. (2) If the entry is authorised under a monitoring warrant, the authorised inspector may require any person on the premises to answer any questions, and produce any document, relating to: (a) the operation of the provision; or (b) the information. (3) If the entry is authorised under section 146 (other than under a monitoring warrant), the authorised inspector may ask the occupier or any other person on the premises to answer any questions, and produce any document, relating to: (a) the operation of the provision; or (b) the information. Note: If an authorised inspector requests a person to answer a question or produce a document under this subsection, the person is not required to comply with the request. (4) A person is not subject to a requirement under subsection (2) if: (a) the person does not possess the information or document required; and (b) the person has taken all reasonable steps available to the person to obtain the information or document required and has been unable to obtain it. See also section 192A (privilege against self-incrimination and legal Note: professional privilege not abrogated).

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(5) A person commits an offence if:

Part 10 MonitoringDivision 2 Powers of authorised inspectors

Section 146E

- (a) the person is subject to a requirement under subsection (2); and
- (b) the person fails to comply with the requirement.

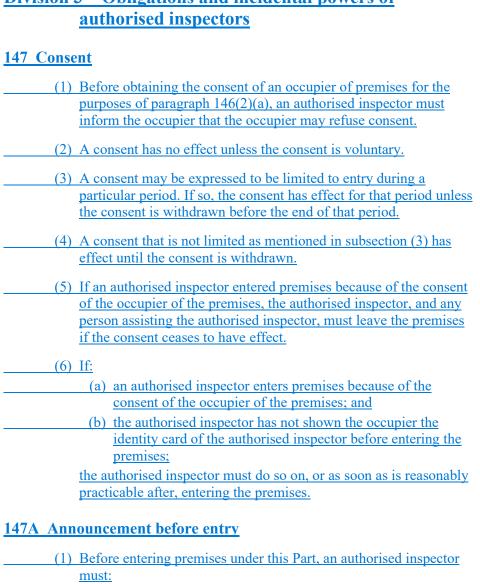
Penalty: 30 penalty units.

Monitoring Part 10

Obligations and incidental powers of authorised inspectors Division 3

Section 147

Division 3—Obligations and incidental powers of authorised inspectors



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(a) announce that the authorised inspector is authorised to enter

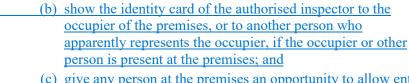
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the premises; and

Part 10 Monitoring

Division 3 Obligations and incidental powers of authorised inspectors

Section 147B



- (c) give any person at the premises an opportunity to allow entry to the premises.
- (2) However, an authorised inspector is not required to comply with subsection (1) if the authorised inspector believes on reasonable grounds that immediate entry to the premises is required:
 - (a) to ensure the health or safety of a person; or
 - (b) to prevent serious damage to the environment; or
 - (c) for entry under a monitoring warrant—to ensure that the effective execution of the warrant is not frustrated.

(3) If:

- (a) an authorised inspector does not comply with subsection (1) because of subsection (2); and
- (b) the occupier of the premises, or another person who apparently represents the occupier, is present at the premises; the authorised inspector must, as soon as practicable after entering the premises, show the identity card of the authorised inspector to the occupier or other person.

147B Use of force

In exercising powers under this Part, an authorised inspector who enters premises under a monitoring warrant may use such force against things as is necessary and reasonable in the circumstances.

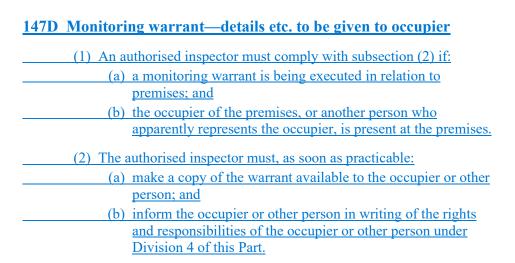
Note: Any use of force by a person assisting will be at the direction of an authorised inspector (see subsection 143(3)).

147C Monitoring warrant—authorised inspector to be in possession

An authorised inspector executing a monitoring warrant must be in possession of the warrant or a copy of the warrant.

Monitoring Part 10 Obligations and incidental powers of authorised inspectors **Division 3**

Section 147D



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Part 10 MonitoringDivision 4 Occupier's rights and responsibilities

Section 148

Division 4—Occupier's rights and responsibilities

148 Right to observe execution of monitoring warrant

- (1) The occupier of premises to which a monitoring warrant relates, or another person who apparently represents the occupier, is entitled to observe the execution of the monitoring warrant if the occupier or other person is present at the premises while the warrant is being executed.
- (2) The right to observe the execution of the warrant ceases if the occupier or other person impedes that execution.
- (3) This section does not prevent the execution of the warrant in 2 or more areas of the premises at the same time.

148A Responsibility to provide facilities and assistance

- (1) Subsection (2) applies if:
 - (a) an authorised inspector enters premises under this Part; and
 - (b) the entry is not authorised only because the occupier of the premises consented to the entry.
 - (2) The occupier of the premises, or another person who apparently represents the occupier, must provide the authorised inspector and any person assisting the authorised inspector with all reasonable facilities and assistance for the effective exercise of their powers.
- (3) A person commits an offence if the person fails to comply with subsection (2).

Penalty: 30 penalty units.

Monitoring Part 10 Monitoring warrants Division 5

Section 149

Division 5—Monitoring warrants

149 Monitoring warrants

- (1) An authorised inspector may apply to an issuing officer for a warrant under this section in relation to premises.
- (2) The issuing officer may issue the warrant if the issuing officer is satisfied, by information on oath or affirmation, that it is reasonably necessary that one or more authorised inspectors should have access to the premises for the purposes of determining:
 - (a) whether a provision that is subject to monitoring under this Part has been, or is being, complied with; or
 - (b) whether information subject to monitoring under this Part is correct.
- (3) However, the issuing officer must not issue the warrant unless the authorised inspector or some other person has given to the issuing officer, either orally or by affidavit, such further information (if any) as the issuing officer requires concerning the grounds on which the issue of the warrant is being sought.
- (4) The warrant must:
 - (a) describe the premises to which the warrant relates; and
 - (b) state that the warrant is issued under this section; and
 - (c) state the purpose for which the warrant is issued; and
 - (d) authorise one or more authorised inspectors (whether or not named in the warrant) from time to time while the warrant remains in force:
 - (i) to enter the premises; and
 - (ii) to exercise the powers set out in this Part in relation to the premises; and
 - (e) state whether entry is authorised to be made at any time of the day or during specified hours of the day; and
 - (f) specify the day (not more than 3 months after the issue of the warrant) on which the warrant ceases to be in force.

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Part 10 Monitoring

Division 6 Extension of periods in which things secured

Section 150

Division 6—Extension of periods in which things secured

150 Extension of periods in which things secured

- (1) This section applies where an authorised inspector applies to an issuing officer under subsection 146C(6) for an extension of the period during which a thing may be secured.
- (2) The issuing officer may, by order, grant an extension of the period if the issuing officer is satisfied, by information on oath or affirmation, that it is necessary to secure the thing to ensure that the thing is not destroyed, altered or otherwise interfered with.
- (3) However, the issuing officer must not grant the extension unless the authorised inspector or some other person has given to the issuing officer, either orally or by affidavit, such further information (if any) as the issuing officer requires concerning the grounds on which the extension is being sought.
 - (4) The order extending the period must:
 - (a) describe the thing to which the order relates; and
 - (b) state the period for which the extension is granted; and
 - (c) state that the order is made under this section; and
 - (d) state that the authorised inspector is authorised to secure the thing for that period.

Investigation Part 10A
Outline and operation of this Part Division 1

Section 151

Part 10A—Investigation

Division 1—Outline and operation of this Part

151 Simplified outline

The following is a simplified outline of this Part:

This Part provides for gathering material that relates to the contravention of offence provisions and civil penalty provisions.

An authorised inspector may enter premises if the authorised inspector suspects on reasonable grounds that there may be material on the premises related to the contravention of an offence provision or a civil penalty provision that is subject to investigation under this Part.

Entry must be with the consent of the occupier of the premises or under an investigation warrant.

An authorised inspector who enters premises may exercise investigation powers. The authorised inspector may be assisted by other persons if that assistance is necessary and reasonable.

151A Provisions subject to investigation

A provision is *subject to investigation* under this Part if it is:

- (a) an offence against this Act; or
- (b) a civil penalty provision of this Act; or
- (c) an offence against the *Crimes Act 1914* or the *Criminal Code* that relates to this Act.

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Part 10A Investigation **Division 2** Powers of authorised inspectors

Section 152

Division 2—Powers of authorised inspectors

Subdivision A—Investigation powers

152 Entering premises by consent or under a warrant

- (1) An authorised inspector may enter any premises and exercise the investigation powers if the authorised inspector suspects on reasonable grounds that there may be evidential material:
 - (a) on the premises; or
 - (b) available by using or operating a thing on the premises.
 - Note: The investigation powers are set out in sections 152A, 152B and
 - (2) However, an authorised inspector is not authorised to enter the premises unless:
 - (a) the occupier of the premises has consented to the entry; or
 - (b) the entry is made under an investigation warrant.

Note: If entry to the premises is with the occupier's consent, the authorised inspector must leave the premises if the consent ceases to have effect (see section 153).

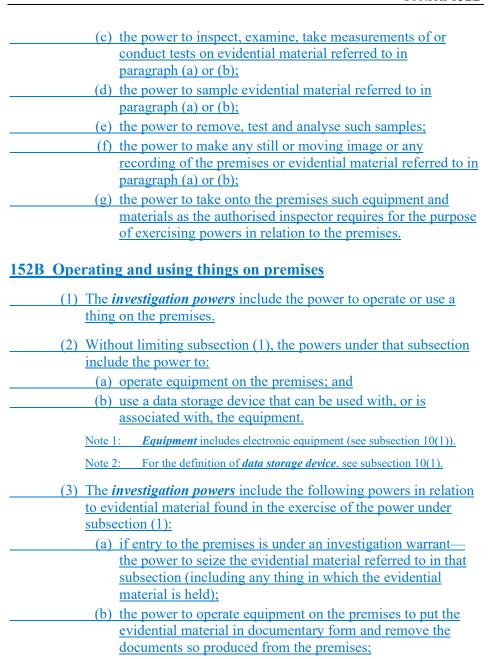
152A General investigation powers

The following are the *investigation powers* that an authorised inspector may exercise in relation to premises under section 152:

- (a) if entry to the premises is with the occupier's consent—the power to search the premises and any thing on the premises for the evidential material the authorised inspector suspects on reasonable grounds may be on the premises;
- (b) if entry to the premises is under an investigation warrant:
 - (i) the power to search the premises and any thing on the premises for the kind of evidential material specified in the warrant; and
 - (ii) the power to seize evidential material of that kind if the authorised inspector finds it on the premises;

Investigation Part 10A
Powers of authorised inspectors Division 2

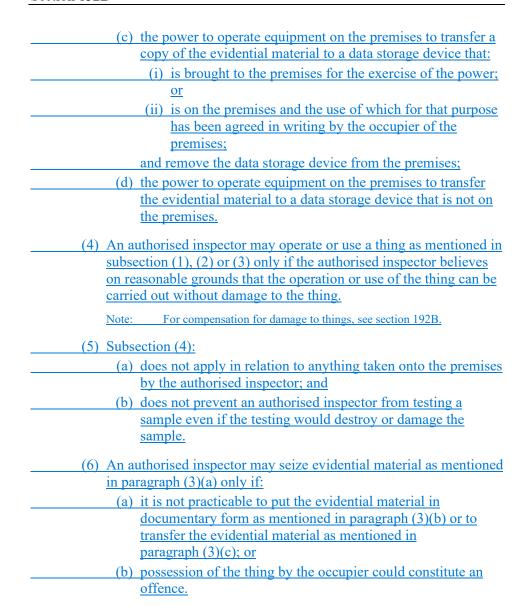
Section 152B



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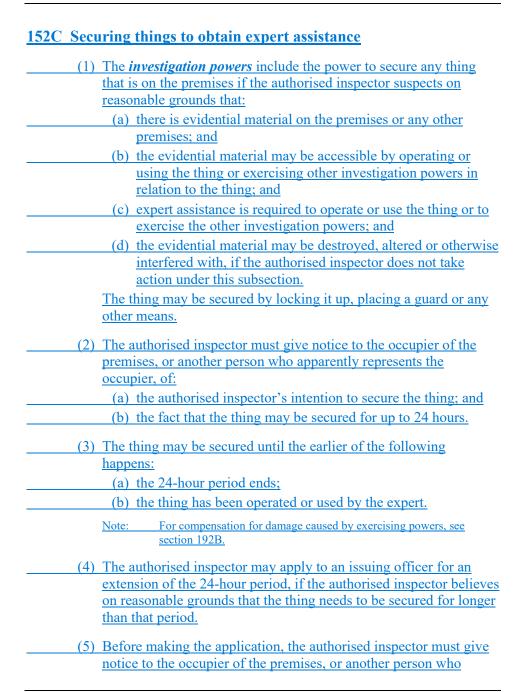
Part 10A InvestigationDivision 2 Powers of authorised inspectors

Section 152B



Investigation Part 10A
Powers of authorised inspectors Division 2

Section 152C



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Part 10A InvestigationDivision 2 Powers of authorised inspectors

Section 152D

apparently represents the occupier, of the authorised inspector's intention to apply for an extension. The occupier or other person is entitled to be heard in relation to that application.

(6) The 24-hour period may be extended more than once.

Note: For the process by which an issuing officer may extend the period, see section 157.

<u>Subdivision B—Powers to ask questions and seek production of</u> documents

152D Asking questions and seeking production of documents

- (1) This section applies if an authorised inspector enters premises to search for evidential material.
- (2) If the entry is authorised because the occupier of the premises consented to the entry, the authorised inspector may ask the occupier to answer any questions, and produce any document, relating to evidential material.

Note: It is not an offence if the person does not comply with the request.

- (3) If the entry is authorised by an investigation warrant, the authorised inspector may require any person on the premises to answer any questions, and produce any document, relating to evidential material of the kind specified in the warrant.
 - (4) A person is not subject to a requirement under subsection (3) if:
 - (a) the person does not possess the information or document required; and
 - (b) the person has taken all reasonable steps available to the person to obtain the information or document required and has been unable to obtain it.
 - (5) A person commits an offence if:
 - (a) the person is subject to a requirement under subsection (3); and
- (b) the person fails to comply with the requirement.

Investigation Part 10A
Powers of authorised inspectors Division 2

Section 152D

Penalty: 30 penalty units.

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Part 10A Investigation

Division 3 Obligations and incidental powers of authorised inspectors

Section 153

<u>Division 3—Obligations and incidental powers of</u> authorised inspectors

153 Consent (1) Before obtaining the consent of an occupier of premises for the purposes of paragraph 152(2)(a), an authorised inspector must inform the occupier that the occupier may refuse consent. (2) A consent has no effect unless the consent is voluntary. (3) A consent may be expressed to be limited to entry during a particular period. If so, the consent has effect for that period unless the consent is withdrawn before the end of that period. (4) A consent that is not limited as mentioned in subsection (3) has effect until the consent is withdrawn. (5) If an authorised inspector entered premises because of the consent of the occupier of the premises, the authorised inspector, and any person assisting the authorised inspector, must leave the premises if the consent ceases to have effect. (6) If: (a) an authorised inspector enters premises because of the consent of the occupier of the premises; and (b) the authorised inspector has not shown the occupier the identity card of the authorised inspector before entering the premises; the authorised inspector must do so on, or as soon as is reasonably practicable after, entering the premises. 153A Announcement before entry under warrant (1) Before entering premises under an investigation warrant, an authorised inspector must: (a) announce that the authorised inspector is authorised to enter the premises; and

Investigation Part 10A Obligations and incidental powers of authorised inspectors Division 3

Section 153B (b) show the identity card of the authorised inspector to the occupier of the premises, or to another person who apparently represents the occupier, if the occupier or other person is present at the premises; and (c) give any person at the premises an opportunity to allow entry to the premises. (2) However, an authorised inspector is not required to comply with subsection (1) if the authorised inspector believes on reasonable grounds that immediate entry to the premises is required: (a) to ensure the health or safety of a person; or (b) to prevent serious damage to the environment; or (c) to ensure that the effective execution of the warrant is not frustrated. (3) If: (a) an authorised inspector does not comply with subsection (1) because of subsection (2); and (b) the occupier of the premises, or another person who apparently represents the occupier, is present at the premises; the authorised inspector must, as soon as practicable after entering the premises, show the identity card of the authorised inspector to the occupier or other person. 153B Authorised inspector to be in possession of warrant An authorised inspector executing an investigation warrant must be in possession of: (a) the warrant issued by the issuing officer under section 156, or a copy of the warrant as so issued; or (b) the form of warrant completed under subsection 156A(6), or a copy of the form as so completed. 153C Details of warrant etc. to be given to occupier (1) An authorised inspector must comply with subsection (2) if:

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Part 10A Investigation

Division 3 Obligations and incidental powers of authorised inspectors

Section 153D

- (a) an investigation warrant is being executed in relation to premises; and
 - (b) the occupier of the premises, or another person who apparently represents the occupier, is present at the premises.
- (2) The authorised inspector executing the warrant must, as soon as practicable:
 - (a) do one of the following:
 - (i) if the warrant was issued under section 156—make a copy of the warrant available to the occupier or other person (which need not include the signature of the issuing officer who issued it);
 - (ii) if the warrant was signed under section 156A—make a copy of the form of warrant completed under subsection 156A(6) available to the occupier or other person; and
 - (b) inform the occupier or other person in writing of the rights and responsibilities of the occupier or other person under Division 4.

153D Using force in executing an investigation warrant

In executing an investigation warrant:

- (a) an authorised inspector may use such force against things as is necessary and reasonable in the circumstances; and
- (b) a person assisting the authorised inspector may use such force against things as is necessary and reasonable in the circumstances.

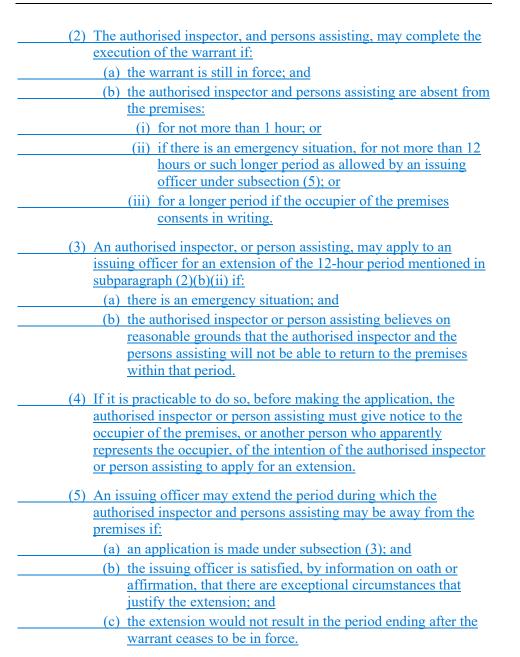
Note: Persons assisting are subject to directions by the authorised inspector (see subsection 143(3)).

153E Completing execution after temporary cessation

(1) This section applies if an authorised inspector, and all persons assisting, who are executing an investigation warrant in relation to premises temporarily cease its execution and leave the premises.

Investigation Part 10A Obligations and incidental powers of authorised inspectors Division 3

Section 153E



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Part 10A Investigation

Division 3 Obligations and incidental powers of authorised inspectors

Section 153F



An authorised inspector, and any persons assisting, may complete the execution of a warrant that has been stopped by an order of a court if:

- (a) the order is later revoked or reversed on appeal; and
- (b) the warrant is still in force when the order is revoked or reversed.

Investigation Part 10A Occupier's rights and responsibilities Division 4

Section 154

Division 4—Occupier's rights and responsibilities

154 Right to observe execution of warrant

- (1) The occupier of premises to which an investigation warrant relates, or another person who apparently represents the occupier, is entitled to observe the execution of the investigation warrant if the occupier or other person is present at the premises while the warrant is being executed.
- (2) The right to observe the execution of the warrant ceases if the occupier or other person impedes that execution.
- (3) This section does not prevent the execution of the warrant in 2 or more areas of the premises at the same time.

154A Responsibility to provide facilities and assistance

- (1) The occupier of premises to which an investigation warrant relates, or another person who apparently represents the occupier, must provide:
 - (a) an authorised inspector executing the warrant; and
 - (b) any person assisting the authorised inspector; with all reasonable facilities and assistance for the effective exercise of their powers.
 - (2) A person commits an offence if the person fails to comply with subsection (1).

Penalty: 30 penalty units.

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Part 10A InvestigationDivision 5 General provisions relating to seizure

Section 155

Division 5—General provisions relating to seizure

155 Copies of seized things to be provided

- (1) This section applies if:
 - (a) an investigation warrant is being executed in relation to premises; and
 - (b) an authorised inspector seizes any of the following from the premises under this Part:
 - (i) a document, film, computer file or other thing that can be readily copied;
 - (ii) a data storage device, the information in which can be readily copied.
- (2) The occupier of the premises, or another person who apparently represents the occupier and who is present when the warrant is executed, may request the authorised inspector to give a copy of the thing or the information to the occupier or other person.
- (3) The authorised inspector must comply with the request as soon as practicable after the seizure.
 - (4) However, the authorised inspector is not required to comply with the request if possession of the thing or information by the occupier or other person could constitute an offence.

155A Receipts for seized things

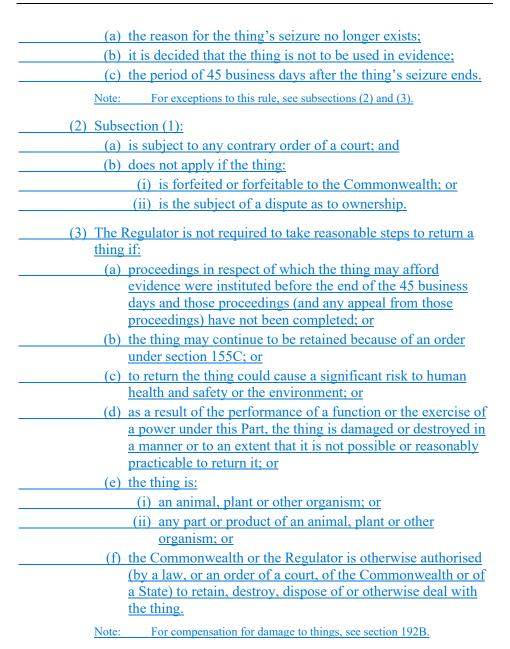
- (1) The authorised inspector must provide a receipt for a thing that is seized under this Part or section 159A.
- (2) One receipt may cover 2 or more things seized.

155B Return of seized things

(1) The Regulator must take reasonable steps to return a thing seized under this Part or section 159A when the earliest of the following happens:

Investigation Part 10A General provisions relating to seizure Division 5

Section 155B



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Part 10A InvestigationDivision 5 General provisions relating to seizure

Section 155C

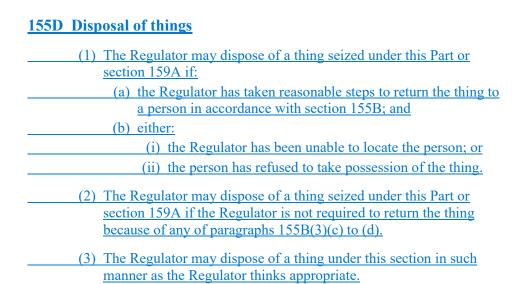
(4) A thing that is required to be returned under this section must be returned to the person from whom it was seized (or to the owner if that person is not entitled to possess it).

155C Issuing officer may permit a thing to be retained

- (1) The Regulator may apply to an issuing officer for an order permitting the retention of a thing seized under this Part or section 159A for a further period if proceedings in respect of which the thing may afford evidence have not commenced before the end of:
 - (a) 45 business days after the seizure; or
 - (b) a period previously specified in an order of an issuing officer under this section.
 - (2) Before making the application, the Regulator must:
 - (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 Regulator believes to have such an interest of the proposed application.
 - (3) Any person notified under paragraph (2)(b) is entitled to be heard in relation to the application.
 - (4) The issuing officer may order that the thing may continue to be retained for a period specified in the order if the issuing officer is satisfied that it is necessary for the thing to continue to be retained:
 - (a) for the purposes of an investigation as to whether an offence provision or a civil penalty provision that is subject to investigation under this Part has been contravened; or
 - (b) to enable evidence of a contravention mentioned in paragraph (a) to be secured for the purposes of a prosecution or an action to obtain a civil penalty order.
 - (5) The period specified must not exceed 3 years.

Investigation Part 10A
General provisions relating to seizure Division 5

Section 155D



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Part 10A Investigation

Division 6 Investigation warrants

Section 156

Division 6—Investigation warrants

156 Investigation warrants (1) An authorised inspector may apply to an issuing officer for a warrant under this section in relation to premises. (2) The issuing officer may issue the warrant if the issuing officer is satisfied, by information on oath or affirmation, that there are reasonable grounds for suspecting that there is, or there may be within the next 72 hours, evidential material: (a) on the premises; or (b) available by using or operating a thing on the premises. (3) However, the issuing officer must not issue the warrant unless the authorised inspector or some other person has given to the issuing officer, either orally or by affidavit, such further information (if any) as the issuing officer requires concerning the grounds on which the issue of the warrant is being sought. (4) The warrant must: (a) state the offence provision or offence provisions, or civil penalty provision or civil penalty provisions, to which the warrant relates; and (b) describe the premises to which the warrant relates; and (c) state that the warrant is issued under this Division; and (d) specify the kinds of evidential material to be searched for under the warrant; and (e) state that evidential material of the kind specified may be seized under the warrant; and (f) state that the person executing the warrant may seize any other thing found in the course of executing the warrant if the person believes on reasonable grounds that the thing is evidential material of a kind not specified in the warrant; and (g) name one or more authorised inspectors; and (h) authorise the authorised inspectors named in the warrant:

(i) to enter the premises; and

Investigation Part 10A
Investigation warrants Division 6

Section 156A (ii) to exercise the powers set out in this Part in relation to the premises; and (i) state whether entry is authorised to be made at any time of the day or during specified hours of the day; and (i) specify the day (not more than 1 week after the issue of the warrant) on which the warrant ceases to be in force. 156A Investigation warrants by telephone, fax etc. (1) An authorised inspector may apply to an issuing officer by telephone, fax or other electronic means for a warrant under section 156 in relation to premises: (a) in an urgent case; or (b) if the delay that would occur if an application were made in person would frustrate the effective execution of the warrant. (2) The issuing officer: (a) may require communication by voice to the extent that it is practicable in the circumstances; and (b) may make a recording of the whole or any part of any such communication by voice. (3) Before applying for the warrant, the authorised inspector must prepare information of the kind mentioned in subsection 156(2) in relation to the premises that sets out the grounds on which the warrant is sought. If it is necessary to do so, the authorised inspector may apply for the warrant before the information is sworn or affirmed. (4) The issuing officer may complete and sign the same warrant that would have been issued under section 156 if, after considering the terms of the information and receiving such further information (if any) that the issuing officer requires, the issuing officer is satisfied that: (a) the warrant should be issued urgently; or (b) the delay that would occur if an application were made in

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person would frustrate the effective execution of the warrant.

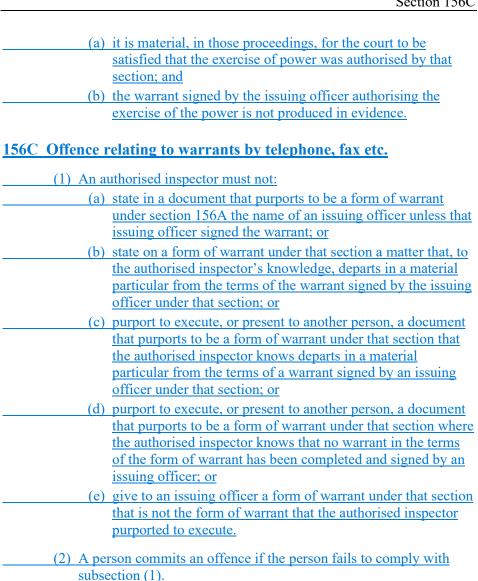
Part 10A Investigation
Division 6 Investigation warrants

Section 156B

(5) After completing and signing the warrant, the issuing officer must
inform the authorised inspector, by telephone, fax or other
electronic means, of:
(a) the terms of the warrant; and
(b) the day on which, and the time at which, the warrant was
signed.
(6) The authorised inspector must then do the following:
(a) complete a form of warrant in the same terms as the warrant
completed and signed by the issuing officer;
(b) state on the form the following:
(i) the name of the issuing officer;
(ii) the day on which, and the time at which, the warrant
was signed;
(c) send the following to the issuing officer:
(i) the form of warrant completed by the authorised
inspector;
(ii) the information referred to in subsection (3), which must have been duly sworn or affirmed.
(7) The authorised inspector must comply with paragraph (6)(c) by the
end of the day after the earlier of the following:
(a) the day on which the warrant ceases to be in force;
(b) the day on which the warrant is executed.
(8) The issuing officer must attach the documents provided under
paragraph (6)(c) to the warrant signed by the issuing officer.
156B Authority of warrant
(1) A form of warrant duly completed under subsection 156A(6) is
authority for the same powers as are authorised by the warrant
signed by the issuing officer under subsection 156A(4).
(2) In any proceedings, a court is to assume (unless the contrary is
proved) that an exercise of power was not authorised by a warrant under section 156A if:
under Section 130A II.

Investigation Part 10A Investigation warrants Division 6

Section 156C



Penalty: Imprisonment for 2 years.

Part 10A InvestigationDivision 7 Extension of periods in which things secured

Section 157

Division 7—Extension of periods in which things secured

157 Extension of periods in which things secured

- (1) This section applies where an authorised inspector applies to an issuing officer under subsection 152C(4) for an extension of the period during which a thing may be secured.
- (2) The issuing officer may, by order, grant an extension of the period if the issuing officer is satisfied, by information on oath or affirmation, that it is necessary to secure the thing in order to prevent evidential material from being destroyed, altered or otherwise interfered with.
- (3) However, the issuing officer must not grant the extension unless the authorised inspector or some other person has given to the issuing officer, either orally or by affidavit, such further information (if any) as the issuing officer requires concerning the grounds on which the extension is being sought.
- (4) The order extending the period must:
 - (a) describe the thing to which the order relates; and
 - (b) state the period for which the extension is granted; and
 - (c) state that the order is made under this section; and
 - (d) state that the authorised inspector is authorised to secure the thing for that period.

Additional monitoring and investigation powers Part 10B Simplified outline Division 1

Section 158

Part 10B—Additional monitoring and investigation powers

Division 1—Simplified outline

158 Simplified outline

The following is a simplified outline of this Part:

This Part provides authorised inspectors and the Regulator with additional monitoring and investigation powers.

<u>Division 2 of this Part provides authorised inspectors with the</u> power to search and seize certain goods arriving in Australia or in an external Territory by ship or aircraft.

Division 3 of this Part allows the Regulator to require a person to produce information, documents or things if the person is, or has been, dealing with a GMO, and the information, documents or things are relevant to the performance of the Regulator's functions.

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Part 10B Additional monitoring and investigation powersDivision 2 Power to search goods, baggage etc.

Section 159

Division 2—Power to search goods, baggage etc.

159 Power to search goods, baggage etc.

- (1) This section applies to any goods that are to be, are being, or have been, taken off a ship that voyages, or an aircraft that flies, between:
 - (a) a place outside Australia and a place in Australia; or
 - (b) a place outside an external Territory and a place in that Territory.
 - (2) If an authorised 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 authorised inspector may:
 - (a) examine the goods; or
 - (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.
 - (3) An authorised inspector may require a person who owns, is carrying or is otherwise associated with, or appears to the authorised inspector to be associated with, goods to which this section applies, to answer any questions in respect of the goods.
 - (4) A person commits an offence if:
 - (a) the person is subject to a requirement under subsection (3); and
 - (b) the person fails to comply with the requirement.

Penalty: 30 penalty units.

159A Seizure of goods

An authorised inspector may seize goods mentioned in section 159 if the authorised inspector has reasonable grounds to suspect that the goods are evidential material.

Additional monitoring and investigation powers Part 10B Power to search goods, baggage etc. Division 2

Section 159A

Note: For return etc. of goods seized under this section, see Division 5 of Part 10A.

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Part 10B Additional monitoring and investigation powersDivision 3 Powers to require persons to produce information and documents

Section 160

<u>Division 3—Powers to require persons to produce</u> information and documents

160 Notice to produce (1) The Regulator may give a notice to a person under subsection (2) if the Regulator believes, on reasonable grounds, that the person: (a) is, or has been, dealing with a GMO; and (b) has information, a document or thing that is relevant to the performance of the Regulator's functions. (2) The Regulator may, by notice in writing given to the person, require the person to do either or both of the following: (a) give any such information as is specified in the notice to the Regulator; (b) produce any such document or thing as is specified in the notice to the Regulator. (3) The notice must: (a) be served on the person; and (b) specify the period within which the person must comply with the notice: and (c) set out the effect of subsection (6). (4) The period specified under paragraph (3)(b) must be at least 10 business days after the notice is served on the person. (5) The person must comply with the notice within the period specified in the notice, or within such longer period as the Regulator allows. Section 192A (protection from self-incrimination etc.) may apply to Note: the giving of information or the production of documents or things under this section. (6) A person commits an offence if: (a) the person is subject to a requirement under subsection (2);

(b) the person fails to comply with the requirement:

Additional monitoring and investigation powers Part 10B Powers to require persons to produce information and documents Division 3

Section 160

- (i) unless subparagraph (ii) applies—within the period specified in the notice; or
- (ii) if the Regulator has allowed the person a longer period under subsection (5)—within such longer period.

Penalty: Imprisonment for 6 months or 30 penalty units.

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Part 10C—Emergency powers

161 Simplified outline

The following is a simplified outline of this Part:

This Part provides an authorised inspector with emergency powers.

An authorised inspector may enter premises, search and secure things, and require a person to comply with the Act or an instrument made under this Act, in particular circumstances where the actions are necessary to avoid a significant risk to human health and safety or the environment.

161A Powers available to authorised inspectors for dealing with dangerous situations

(1) This section applies if:

- (a) an authorised inspector has reasonable grounds for suspecting that there may be on any premises a particular thing in respect of which this Act or a legislative instrument made under this Act has not been complied with; and
- (b) the authorised inspector considers that it is necessary to exercise powers under this section in order to avoid a significant risk to human health and safety or the environment.

Note: Powers under this section may be exercised without either a warrant or the consent of an occupier.

- (2) The authorised inspector may do any of the following:
 - (a) enter the premises;
 - (b) search the premises for the thing;
 - (c) secure the thing, if the authorised inspector finds it on the premises, until a warrant is obtained to seize the thing;

Emergency powers Part 10C

Section 161A (d) if the authorised inspector has reasonable grounds for suspecting that a person has not complied with this Act or a legislative instrument made under this Act in respect of the thing—require the person to take such steps as the authorised inspector considers necessary for the person to comply with this Act or the instrument; (e) take such steps, or arrange for such steps to be taken, in relation to the thing as the authorised inspector considers appropriate. (3) The authorised inspector may exercise the powers in subsection (2) only to the extent that it is necessary for the purpose of avoiding a significant risk to human health and safety or the environment. (4) If: (a) the authorised inspector has reasonable grounds for suspecting that a person has not complied with this Act or a legislative instrument made under this Act in respect of the thing; and (b) the Regulator incurs costs because of steps reasonably taken or arranged to be taken by an authorised inspector under paragraph (2)(e); the person is liable to pay to the Commonwealth an amount equal to the costs, and the amount may be recovered by the Commonwealth as a debt due to the Commonwealth in a court of competent jurisdiction.

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Part 11 Enforcement

Division 1 Outline and operation of this Part

Section 162

Part 11—Enforcement

Division 1—Outline and operation of this Part

162 Simplified outline

The following is a simplified outline of this Part:

Division 2 of this Part provides for the use of civil penalties to enforce civil penalty provisions. Civil penalty orders may be sought from a court in relation to contraventions of civil penalty provisions.

Division 3 of this Part provides for the use of infringement notices where an authorised compliance officer reasonably believes that a provision of this Act or a legislative instrument made under this Act has been contravened. A person can be given an infringement notice in relation to a contravention of a provision that is a strict liability offence provision or a civil penalty provision, or both.

Division 4 of this Part provides for accepting and enforcing undertakings relating to compliance with provisions of this Act or a legislative instrument made under this Act. The undertaking may be enforced in a court of competent jurisdiction.

Division 5 of this Part provides for injunctions to be used to enforce provisions of this Act or a legislative instrument made under this Act. Injunctions may be used to restrain a person from contravening a provision of this Act or a legislative instrument made under this Act, or to compel compliance with such a provision.

Division 6 of this Part provides for the Regulator to give directions if the Regulator reasonably believes that a provision of this Act or a legislative instrument made under this Act has been contravened. The Regulator may give a direction to require compliance if it is necessary to do so in order to protect the health and safety of

Enforcement Part 11
Outline and operation of this Part Division 1

Section 162A

people, or to protect the environment or if it is in the public interest.

<u>Division 6 of this Part also provides for the Regulator to give</u> directions in the event a licence or permit is not, or will not be, in force. Division 6 also contains a forfeiture provision.

162A Civil penalty provisions

A provision of this Act is a civil penalty provision if:

- (a) the provision sets out at its foot a pecuniary penalty, or penalties, indicated by the words "Civil penalty"; and
- (b) the provision is a subsection, or a section that is not divided into subsections.

Part 11 EnforcementDivision 2 Civil penalty provisions

Section 163

Division 2—Civil penalty provisions

Subdivision A—Obtaining a civil penalty order

(1) An authorised compliance officer may apply to a court of competent jurisdiction for an order that a person, who is alleged to have contravened a civil penalty provision, pay the Commonwealth a pecuniary penalty. (2) The authorised compliance officer must make the application within 6 years of the alleged contravention. (3) If the court is satisfied that the person has contravened the civil penalty provision, the court may order the person to pay to the Commonwealth such pecuniary penalty for the contravention as the

Note: Subsection (5) sets out the maximum penalty that the court may order the person to pay.

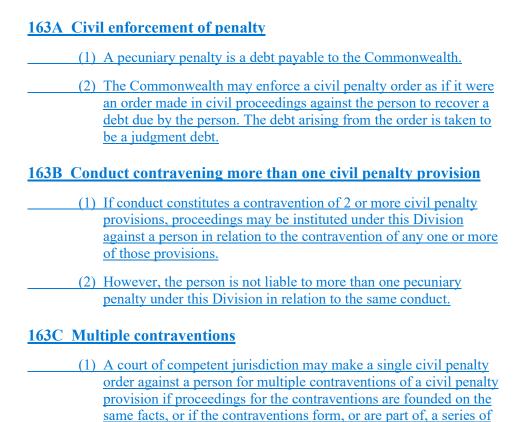
- (4) An order under subsection (3) is a *civil penalty order*.
- (5) The pecuniary penalty must not be more than:

court determines to be appropriate.

- (a) if the person is a body corporate—5 times the pecuniary penalty specified for the civil penalty provision; and
- (b) otherwise—the pecuniary penalty specified for the civil penalty provision.
- (6) In determining the pecuniary penalty, the court must take into account all relevant matters, including:
 - (a) the nature and extent of the contravention; and
 - (b) the nature and extent of any loss or damage suffered because of the contravention; and
 - (c) the circumstances in which the contravention took place; and
 - (d) whether the person has previously been found by a court (including a court in a foreign country) to have engaged in any similar conduct.

Enforcement Part 11 Civil penalty provisions Division 2

Section 163A



contraventions of the same or a similar character.
 Note: For continuing contraventions of civil penalty provisions, see section 163L.

(2) However, the penalty must not exceed the sum of the maximum penalties that could be ordered if a separate penalty were ordered for each of the contraventions.

163D Proceedings may be heard together

A court of competent jurisdiction may direct that 2 or more proceedings for civil penalty orders are to be heard together.

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Part 11 EnforcementDivision 2 Civil penalty provisions

Section 163E

163E Civil evidence and procedure rules for civil penalty orders

A court of competent jurisdiction must apply the rules of evidence and procedure for civil matters when hearing proceedings for a civil penalty order.

Subdivision B—Civil proceedings and criminal proceedings

163F Civil proceedings after criminal proceedings

A court of competent jurisdiction may not make a civil penalty order against a person for a contravention of a civil penalty provision if the person has been convicted of an offence constituted by conduct that is the same, or substantially the same, as the conduct constituting the contravention.

163G Criminal proceedings during civil proceedings

- (1) Proceedings for a civil penalty order against a person for a contravention of a civil penalty provision are stayed if:
 - (a) criminal proceedings are commenced or have already been commenced against the person for an offence; and
 - (b) the offence is constituted by conduct that is the same, or substantially the same, as the conduct alleged to constitute the contravention.
- (2) The proceedings for the order (the *civil proceedings*) may be resumed if the person is not convicted of the offence. Otherwise:
 - (a) the civil proceedings are dismissed; and
 - (b) costs must not be awarded in relation to the civil proceedings.

163H Criminal proceedings after civil proceedings

Criminal proceedings may be commenced against a person for conduct that is the same, or substantially the same, as conduct that would constitute a contravention of a civil penalty provision

Enforcement Part 11 Civil penalty provisions Division 2

Section 163J

regardless of whether a civil penalty order has been made against the person in relation to the contravention.

163J Evidence given in civil proceedings not admissible in criminal proceedings

- (1) Evidence of information given, or evidence of production of documents, by an individual is not admissible in criminal proceedings against the individual if:
 - (a) the individual previously gave the information or produced the documents in proceedings for a civil penalty order against the individual for an alleged contravention of a civil penalty provision (whether or not the order was made); and
 - (b) the conduct alleged to constitute the offence is the same, or substantially the same, as the conduct alleged to constitute the contravention.
- (2) However, subsection (1) does not apply to criminal proceedings in relation to the falsity of the evidence given by the individual in the proceedings for the civil penalty order.

Subdivision C—Miscellaneous

163K Ancillary contravention of civil penalty provisions

- (1) A person must not:
 - (a) attempt to contravene a civil penalty provision; or
 - (b) aid, abet, counsel or procure a contravention of a civil penalty provision; or
 - (c) induce (by threats, promises or otherwise) a contravention of a civil penalty provision; or
 - (d) be in any way, directly or indirectly, knowingly concerned in, or party to, a contravention of a civil penalty provision; or
 - (e) conspire with others to effect a contravention of a civil penalty provision.
 - (2) A person who contravenes subsection (1) in relation to a civil penalty provision is taken to have contravened the provision.

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Part 11 EnforcementDivision 2 Civil penalty provisions

Section 163L

Note: Section 163M (which provides that a person's state of mind does not need to be proven in relation to a civil penalty provision) does not apply to the extent that proceedings relate to the contravention of subsection (1).

163L Continuing contraventions of civil penalty provisions

- (1) If an act or thing is required under a civil penalty provision to be done:
 - (a) within a particular period; or
 - (b) before a particular time;

then the obligation to do that act or thing continues until the act or thing is done (even if the period has expired or the time has passed).

- (2) A person who contravenes a civil penalty provision that requires an act or thing to be done:
 - (a) within a particular period; or
 - (b) before a particular time;

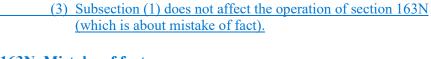
commits a separate contravention of that provision in respect of each day during which the contravention occurs (including the day the relevant civil penalty order is made or any later day).

163M State of mind

- (1) In proceedings for a civil penalty order against a person for a contravention of a civil penalty provision, it is not necessary to prove:
 - (a) the person's intention; or
 - (b) the person's knowledge; or
 - (c) the person's recklessness; or
 - (d) the person's negligence; or
 - (e) any other state of mind of the person.
 - (2) Subsection (1) does not apply to the extent that the proceedings relate to a contravention of subsection 163K(1) (which is about ancillary contravention of civil penalty provisions).

Enforcement Part 11 Civil penalty provisions Division 2

Section 163N



163N Mistake of fact

- (1) A person is not liable to have a civil penalty order made against the person for a contravention of a civil penalty provision if:
 - (a) at or before the time of the conduct constituting the contravention, the person:
 - (i) considered whether or not facts existed; and
 - (ii) was under a mistaken but reasonable belief about those facts; and
 - (b) had those facts existed, the conduct would not have constituted a contravention of the civil penalty provision.
- (2) For the purposes of subsection (1), a person may be regarded as having considered whether or not facts existed if:
 - (a) the person had considered, on a previous occasion, whether those facts existed in the circumstances surrounding that occasion; and
 - (b) the person honestly and reasonably believed that the circumstances surrounding the present occasion were the same, or substantially the same, as those surrounding the previous occasion.
- (3) A person who wishes to rely on subsection (1) or (2) in proceedings for a civil penalty order bears an evidential burden in relation to that matter.

163P Exceptions etc. to civil penalty provisions—burden of proof

If, in proceedings for a civil penalty order against a person for a contravention of a civil penalty provision, the person wishes to rely on any exception, exemption, excuse, qualification or justification provided by the law creating the civil penalty provision, then the person bears an evidential burden in relation to that matter.

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Part 11 EnforcementDivision 2 Civil penalty provisions

Section 163Q

163Q Civil penalty provisions contravened by employees, agents or officers

If an element of a civil penalty provision is done by an employee, agent or officer of a body corporate acting:

- (a) within the actual or apparent scope of the employee's, agent's, or officer's employment; or
- (b) within the employee's, agent's, or officer's actual or apparent authority;

the element must also be attributed to the body corporate.

Enforcement Part 11 Infringement notices Division 3

Section 164

Division 3—Infringement notices

164 Provisions subject to infringement notices

The following provisions are *subject to an infringement notice*under this Division:

(a) section 32A (dealings with GMOs must be authorised);
(b) subsection 33A(1) (breach of condition by licence holder or permit holder);
(c) subsection 33A(2) (breach of condition by former licence holder or permit holder);
(d) section 33C (breach of condition by person covered by GMO licence or GMO permit);
(e) section 33E (breach of condition by person);
(f) section 33G (breach of condition by holder of certification or

- accreditation);(g) section 34A (interference with dealings with GMOs);
- (h) section 34C (false or misleading information or document);
- (i) subsection 167(6) (failure to comply with notice).

164A When an infringement notice may be given

- (1) If an authorised compliance officer believes on reasonable grounds that a person has contravened a provision subject to an infringement notice under this Division, the authorised compliance officer may give to the person an infringement notice for the alleged contravention.
 - (2) The infringement notice must be given within 12 months after the day on which the contravention is alleged to have taken place.
 - (3) A single infringement notice must relate only to a single contravention of a single provision unless subsection (4) applies.
 - (4) An authorised compliance officer may give a person a single infringement notice relating to multiple contraventions of a single provision if:

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Division 3 Infringement notices

Section 164B

(a) the provision requires the person to do a thing within a
particular period or before a particular time; and
(b) the person fails or refuses to do that thing within that period
or before that time; and
(c) the failure or refusal occurs on more than 1 day; and
(d) each contravention is constituted by the failure or refusal on
one of those days.

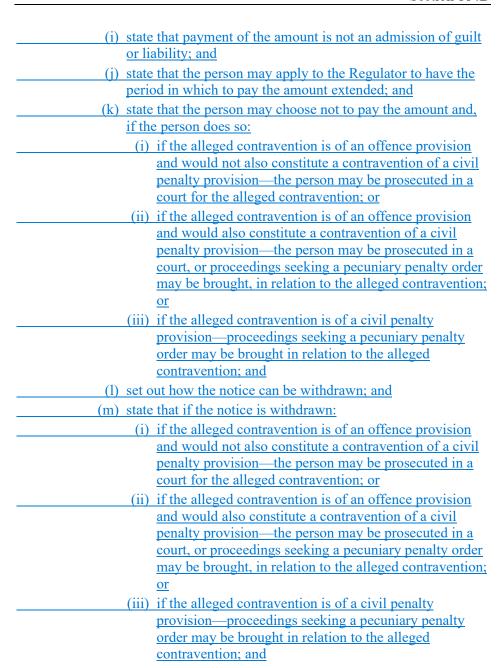
one of those days.
164B Matters to be included in an infringement notice
(1) An infringement notice must:
(a) be identified by a unique number; and
(b) state the day on which it is given; and
(c) state the name of the person to whom the notice is given; and
(d) state the name and contact details of the person who gave the
notice, and that the person is an authorised compliance
officer for the purposes of issuing the infringement notice;
<u>and</u>
(e) give brief details of the alleged contravention, or each alleged
contravention, to which the notice relates, including:
(i) the provision that was allegedly contravened; and
(ii) the maximum penalty that a court could impose for each
contravention, if the provision were contravened; and
(iii) the time (if known) and day of, and the place of, each
alleged contravention; and
(f) state the amount that is payable under the notice; and
(g) give an explanation of how payment of the amount is to be
made; and
(h) state that, if the person to whom the notice is given pays the
amount within 20 business days after the day the notice is
given, then (unless the notice is withdrawn):
(i) proceedings seeking a pecuniary penalty order will not
be brought in relation to the alleged contravention; and

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(ii) if the alleged contravention would also constitute an offence under this Act—the person is not liable to be prosecuted in a court for the alleged contravention; and

Enforcement Part 11 Infringement notices Division 3

Section 164B

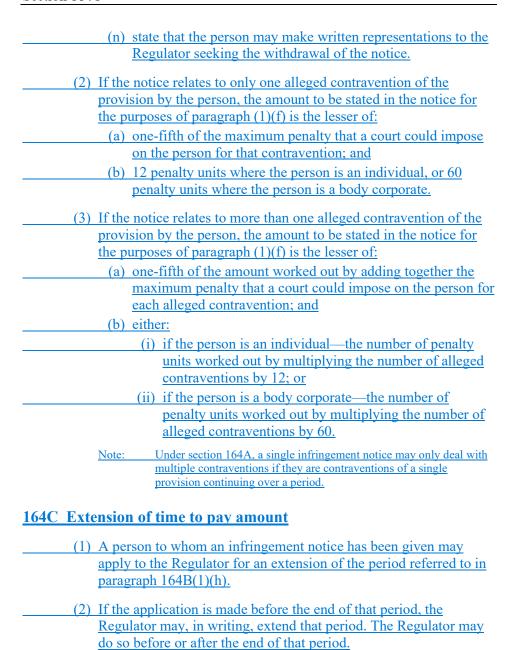


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Part 11 Enforcement

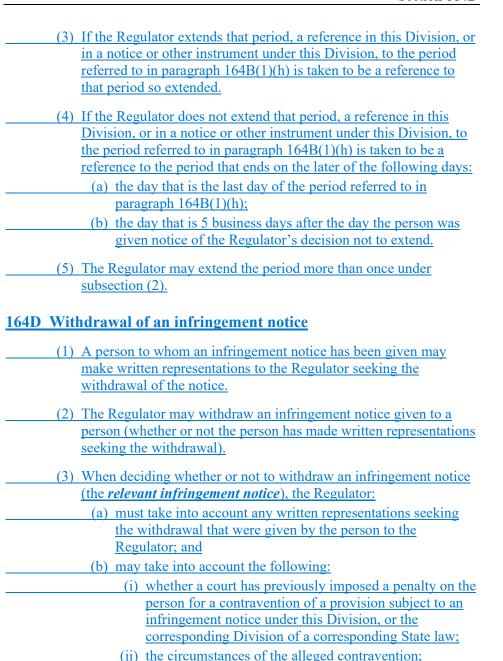
Division 3 Infringement notices

Section 164C



Enforcement Part 11 Infringement notices Division 3

Section 164D

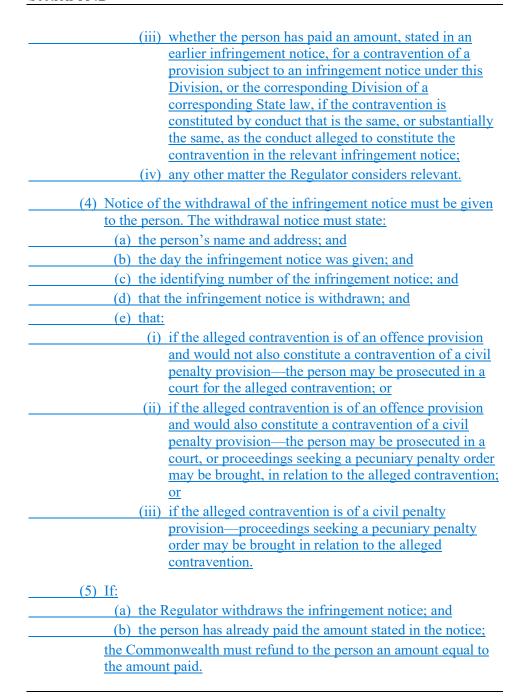


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Part 11 Enforcement

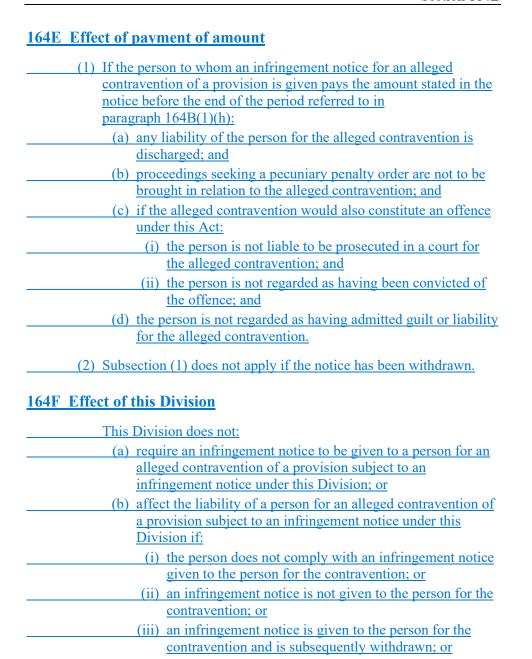
Division 3 Infringement notices

Section 164D



Enforcement Part 11 Infringement notices Division 3

Section 164E



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Part 11 EnforcementDivision 3 Infringement notices

Section 164F

- (c) prevent the giving of 2 or more infringement notices to a person for an alleged contravention of a provision subject to an infringement notice under this Division; or
- (d) limit a court's discretion to determine the amount of a penalty to be imposed on a person who is found to have contravened a provision subject to an infringement notice under this Division.

Enforcement Part 11 Enforceable undertakings Division 4

Section 165

Division 4—Enforceable undertakings

165 Acceptance of undertakings

- (1) The Regulator may accept any of the following undertakings:(a) a written undertaking given by a person that the person will,
 - in order to comply with a provision of this Act or a legislative instrument made under this Act, take specified action;
 - (b) a written undertaking given by a person that the person will, in order to comply with a provision of this Act or a legislative instrument made under this Act, refrain from taking specified action;
 - (c) a written undertaking given by a person that the person will take specified action directed towards ensuring that the person does not contravene a provision of this Act or a legislative instrument made under this Act, or is unlikely to contravene such a provision, in the future.
- (2) The undertaking must be expressed to be an undertaking under this section.
 - (3) The person may withdraw or vary the undertaking at any time, but only with the written consent of the Regulator.
 - (4) The consent of the Regulator is not a legislative instrument.
 - (5) The Regulator may, by written notice given to the person, cancel the undertaking.
 - (6) The Regulator may publish details of an undertaking given under this section on the internet.

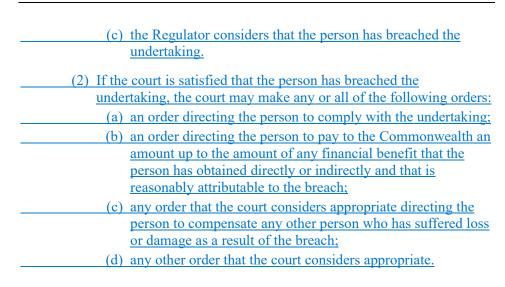
165A Enforcement of undertakings

- (1) The Regulator may apply to a court of competent jurisdiction for an order under subsection (2) if:
 - (a) a person has given an undertaking under section 165; and
 - (b) the undertaking has not been withdrawn or cancelled; and

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Part 11 EnforcementDivision 4 Enforceable undertakings

Section 165A



Enforcement Part 11 Injunctions Division 5

Section 166

Division 5—Injunctions

166 Grant of injunctions

- (1) If a person has engaged, is engaging or is proposing to engage, in conduct in contravention of a provision of this Act or a legislative instrument made under this Act, a court of competent jurisdiction may, on application by the Regulator, grant an injunction:
 - (a) restraining the person from engaging in the conduct; and
 - (b) if, in the court's opinion, it is desirable to do so—requiring the person to do a thing.

(2) If:

- (a) a person has refused or failed, or is refusing or failing, or is proposing to refuse or fail, to do a thing; and
- (b) the refusal or failure was, is or would be a contravention of a provision of this Act or a legislative instrument made under this Act;

the court may, on application by the Regulator, grant an injunction requiring the person to do that thing.

166A Interim injunctions

- (1) Before deciding an application for an injunction under section 166, a court of competent jurisdiction may grant an interim injunction:
 - (a) restraining a person from engaging in conduct; or
 - (b) requiring a person to do a thing.
 - (2) The court must not require an applicant for an injunction under section 166 to give an undertaking as to damages as a condition of granting an interim injunction.

166B Discharging or varying injunctions

A court of competent jurisdiction may discharge or vary an injunction granted by that court under this Division.

Gene Technology Act 2000

Part 11 EnforcementDivision 5 Injunctions

Section 166C



- (1) The power of a court of competent jurisdiction under this Division to grant an injunction restraining a person from engaging in conduct may be exercised:
 - (a) whether or not it appears to the court that the person intends to engage again, 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; and
 - (c) whether or not there is a significant risk to human health and safety or the environment if the person engages in conduct of that kind.
- (2) The power of a court of competent jurisdiction under this Division to grant an injunction requiring a person to do a thing may be exercised:
 - (a) whether or not it appears to the court that the person intends to refuse or fail again, or to continue to refuse or fail, to do that thing; and
 - (b) whether or not the person has previously refused or failed to do that thing; and
 - (c) whether or not there is a significant risk to human health and safety or the environment if the person refuses or fails to do that thing.

166D Other powers of a court unaffected

The powers conferred on a court of competent jurisdiction under this Division are in addition to, and not instead of, any other powers of the court, whether conferred by this Act or otherwise.

Enforcement **Part 11**Other matters **Division 6**

Section 167

Division 6—Other matters

167 Regulator may give directions

- (1) If the Regulator believes, on reasonable grounds, that:
 - (a) the holder of a GMO licence or a GMO permit is not complying with this Act; and
 - (b) either of the following applies:
 - (i) it is necessary to exercise powers under this section in order to protect the health and safety of people or to protect the environment;
 - (ii) it is desirable in the public interest, having regard to the matters specified in subsection (3), for the Regulator to exercise powers under this section;

the Regulator may give directions to the holder, by written notice, requiring the holder, within the period specified in the notice, to take such steps in relation to the thing as are reasonable in the circumstances for the holder to comply with this Act.

- (2) If the Regulator believes on reasonable grounds that:
 - (a) one of the following kinds of persons is not complying with this Act in respect of a thing:
 - (i) a person covered by a GMO licence;
 - (ii) a person covered by a GMO permit;
 - (iii) a person dealing with, or who has dealt with, a GMO specified in an emergency dealing determination;
 - (iv) a person undertaking a notifiable dealing; and
- (b) either of the following applies:
 - (i) it is necessary to exercise powers under this section in order to protect the health and safety of people or to protect the environment;
 - (ii) it is desirable in the public interest, having regard to the matters specified in subsection (3), for the Regulator to exercise powers under this section;

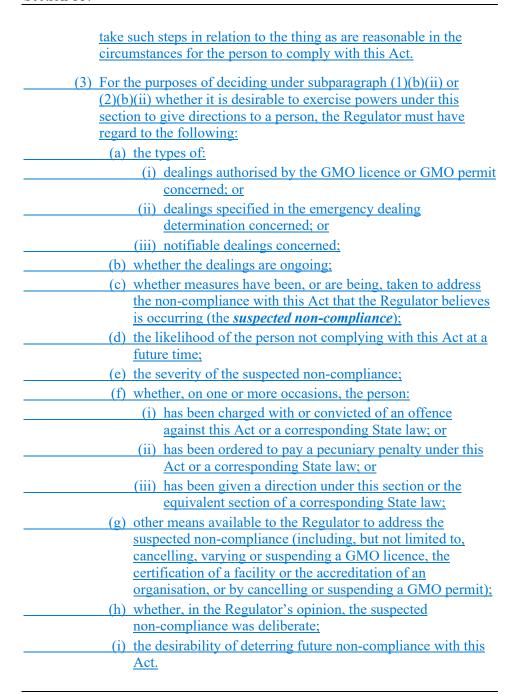
the Regulator may give directions to the person, by written notice, requiring the person, within the period specified in the notice, to

Gene Technology Act 2000

Part 11 Enforcement

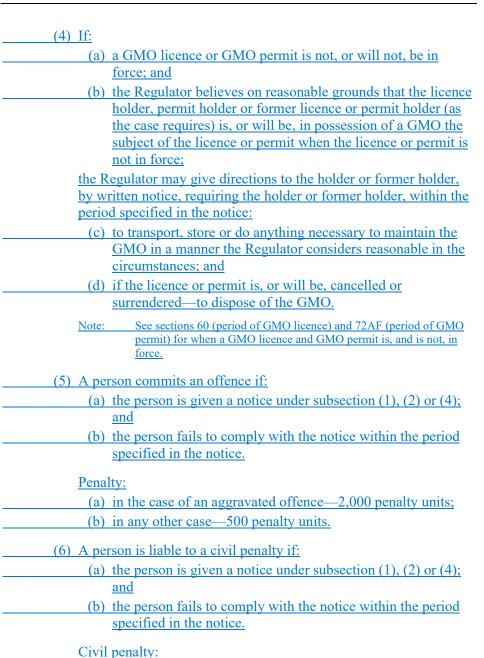
Division 6 Other matters

Section 167



Enforcement Part 11
Other matters Division 6

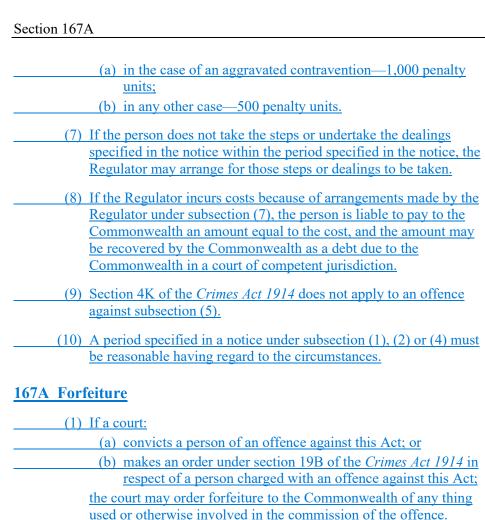
Section 167



Gene Technology Act 2000

Part 11 Enforcement

Division 6 Other matters



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

Powers of inspection Part 11 Simplified outline Division 1

Section 149

Part 11 Powers of inspection

Division 1—Simplified outline

149 Simplified outline

The following is a simplified outline of this Part:

This Part provides for powers of inspection in relation to monitoring and offences.

Division 2 provides for the appointment of inspectors.

Divisions 3 to 9 deal with the powers and obligations of inspectors, and the rights and responsibilities of an occupier of premises when an inspector seeks to exercise powers.

Division 10 sets out procedures relating to monitoring warrants and offence related warrants.

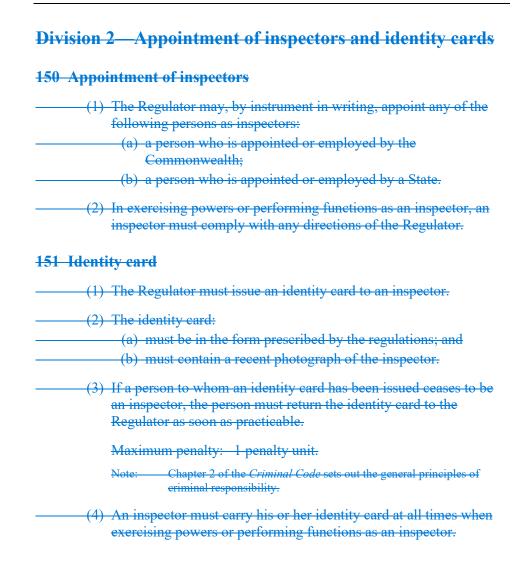
This Part does not limit the conditions to which a licence or an emergency dealing determination can be subject, and section 64 imposes a condition in relation to monitoring dealings with GMOs.

Gene Technology Act 2000

Part 11 Powers of inspection

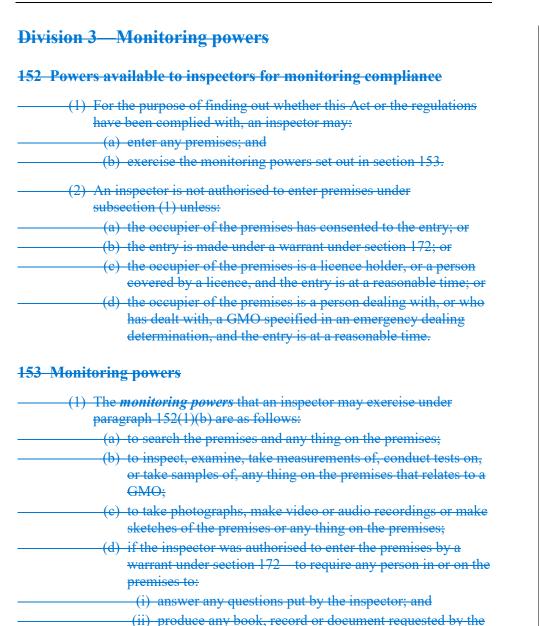
Division 2 Appointment of inspectors and identity cards

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Powers of inspection **Part 11** Monitoring powers **Division 3**

Section 152



Gene Technology Act 2000

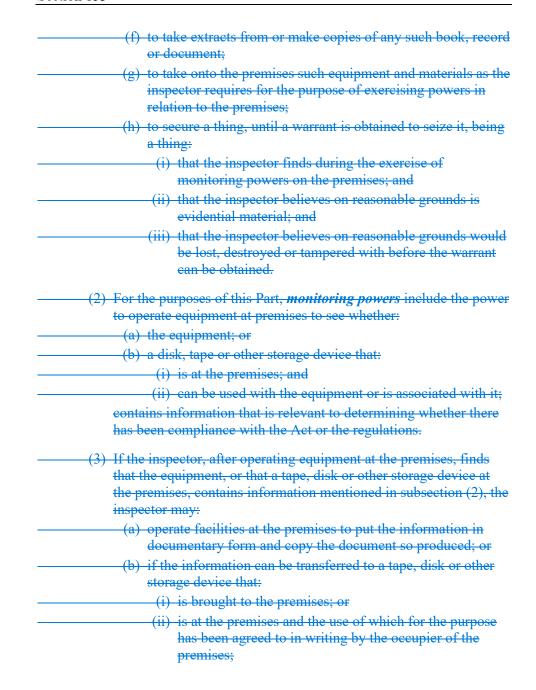
(e) to inspect any book, record or document on the premises;

259

inspector;

Part 11 Powers of inspectionDivision 3 Monitoring powers

Section 153



Powers of inspection Part 11 Monitoring powers Division 3

Section 153

operate the equipment or other facilities to copy the information to the storage device, and remove the storage device from the premises.

Gene Technology Act 2000

Part 11 Powers of inspectionDivision 4 Offence-related powers

Section 154

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; and (b) exercise the powers set out in subsection (3) and section 155; (c) if the entry is under a warrant—seize the evidential material, if the inspector finds it on the premises. (3) If: (a) in the course of searching, in accordance with a warrant, for a particular thing, an inspector finds another thing that the inspector believes on reasonable grounds to be evidential material; 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 paragraph 154(2)(b) are as follows: (a) to search the premises and any thing on the premises for the evidential material;

(b) to inspect, examine, take measurements of, conduct tests on,

or take samples of the evidential material;

Powers of inspection Part 11 Offence-related powers Division 4

Section 156 (c) to take photographs, make video or audio recordings or make sketches of the premises or the evidential material; (d) to take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises. 156 Use of equipment at premises (1) The inspector may operate equipment at the premises to see whether evidential material is accessible by doing so, if the inspector believes on reasonable grounds that the operation of the equipment can be carried out without damage to the equipment. (2) If the inspector, after operating the equipment, finds that evidential material is accessible by doing so, the inspector may: (a) seize the equipment and any disk, tape or other associated device; or (b) if the material can, by using facilities at the premises, be put in documentary form operate the facilities to put the material in that form and seize the documents so produced; or (c) if the material can be transferred to a disk, tape or other storage device that: (i) is brought to the premises; 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. (3) An inspector may seize equipment under paragraph (2)(a) only if: (a) it is not practicable to put the material in documentary form

- (a) it is not practicable to put the material in documentary form as mentioned in paragraph (2)(b) or to copy the material as mentioned in paragraph (2)(c); or
- (b) possession by the occupier of the equipment could constitute an offence.

Gene Technology Act 2000

Part 11 Powers of inspectionDivision 4 Offence-related powers

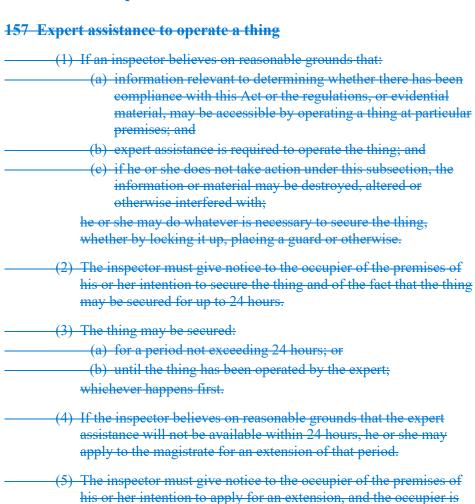
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Section	- 1	1
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(4) An inspector may seize equipment under paragraph (2)(a) or documents under paragraph (2)(b) only if the inspector entered the premises under a warrant.

Powers of inspection Part 11 Expert assistance Division 5

Section 157

Division 5—Expert assistance



entitled to be heard in relation to the application.

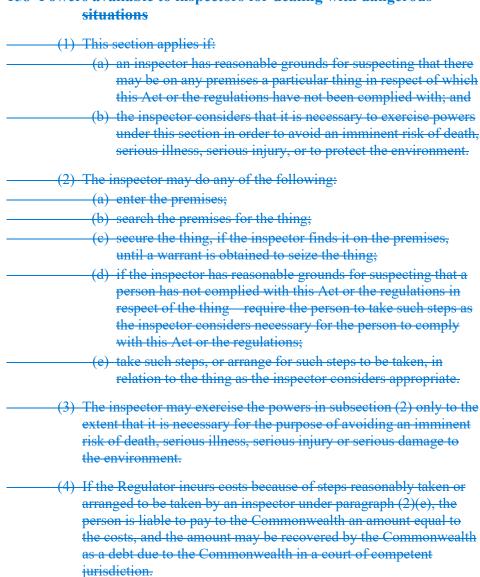
Gene Technology Act 2000

Part 11 Powers of inspection **Division 6** Emergency powers

Section 158

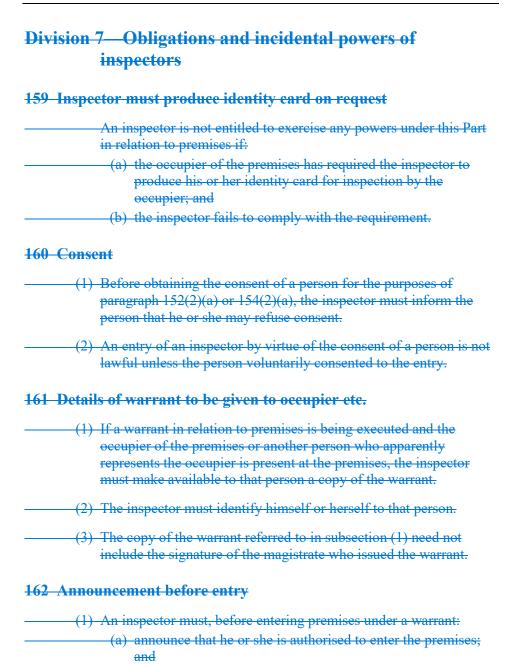
Division 6—Emergency powers

158 Powers available to inspectors for dealing with dangerous



Powers of inspection Part 11 Obligations and incidental powers of inspectors Division 7

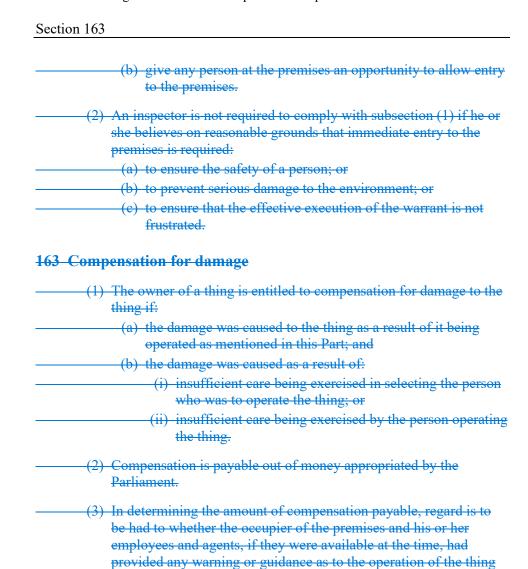
Section 159



Gene Technology Act 2000

Part 11 Powers of inspection

Division 7 Obligations and incidental powers of inspectors

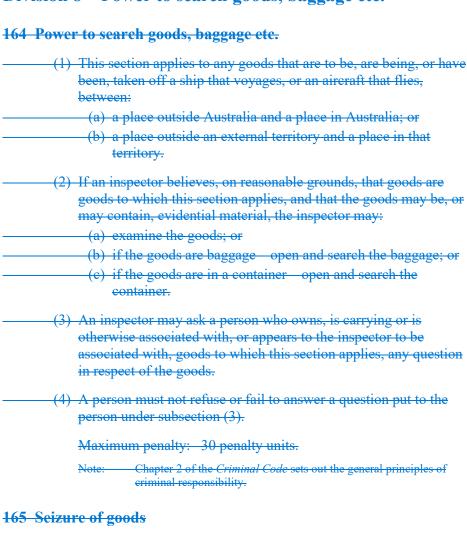


that was appropriate in the circumstances.

Powers of inspection **Part 11** Power to search goods, baggage etc. **Division 8**

Section 164

Division 8—Power to search goods, baggage etc.



Gene Technology Act 2000

An inspector may seize goods mentioned in section 164 if the inspector has reasonable grounds to suspect that the goods are

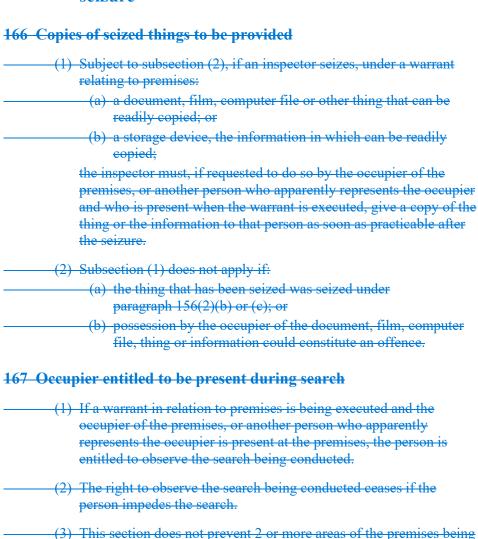
evidential material.

Part 11 Powers of inspection

Division 9 General provisions relating to search and seizure

Section 166

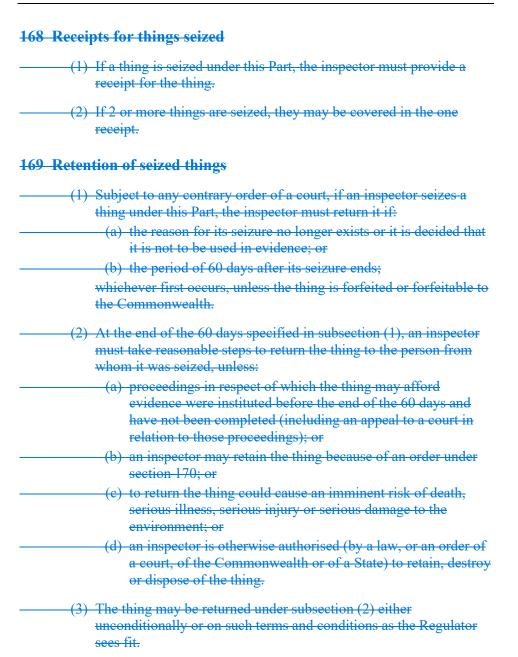
Division 9—General provisions relating to search and seizure



searched at the same time.

Powers of inspection Part 11 General provisions relating to search and seizure Division 9

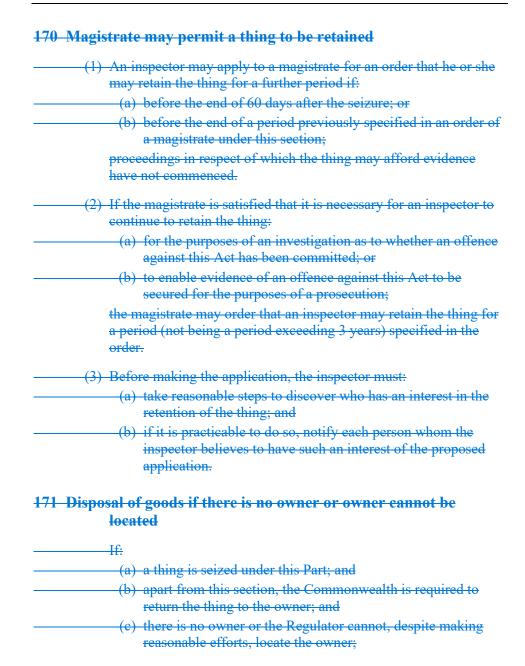
Section 168



Part 11 Powers of inspection

Division 9 General provisions relating to search and seizure

Section 170



Powers of inspection Part 11 General provisions relating to search and seizure Division 9

Section 171

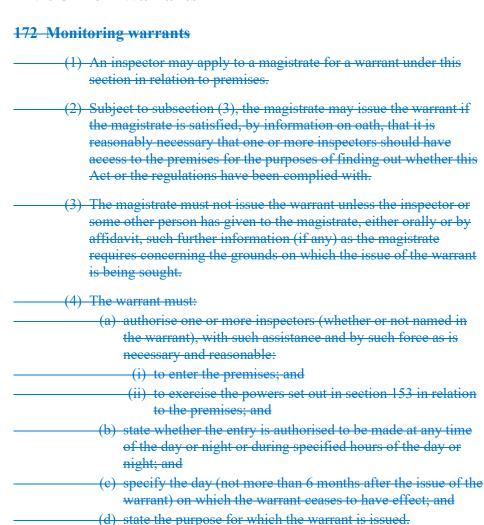
the Regulator may dispose of the thing in such manner as the Regulator thinks appropriate.

Gene Technology Act 2000

Part 11 Powers of inspection
Division 10 Warrants

Section 172

Division 10—Warrants

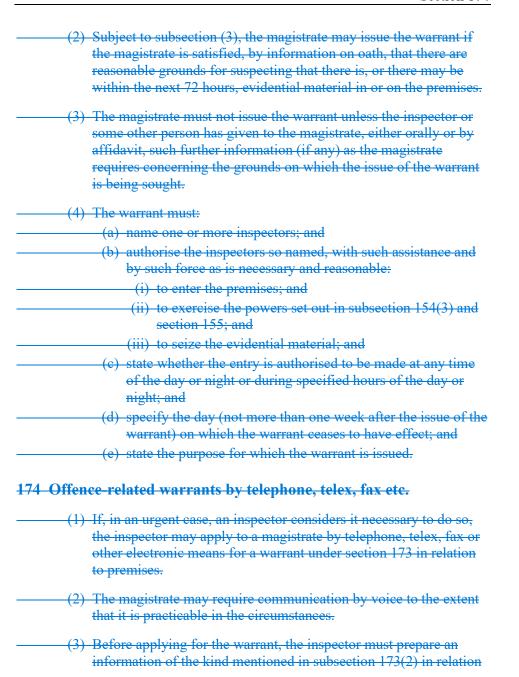


173 Offence-related warrants

(1) An inspector may apply to a magistrate for a warrant under this section in relation to premises.

Powers of inspection Part 11
Warrants Division 10

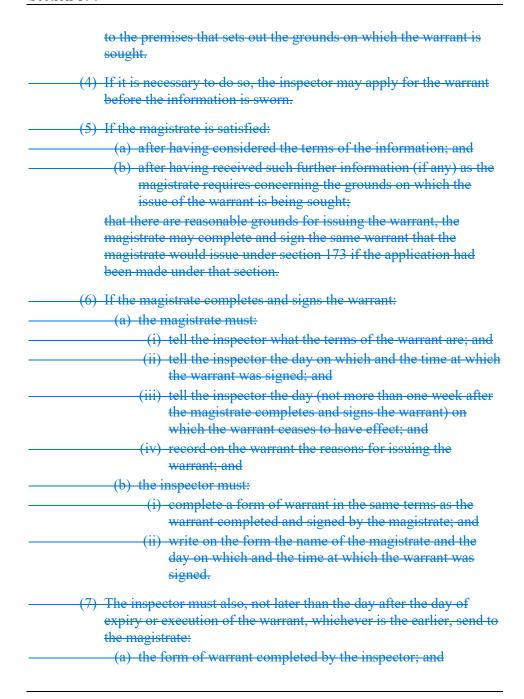
Section 174



Gene Technology Act 2000

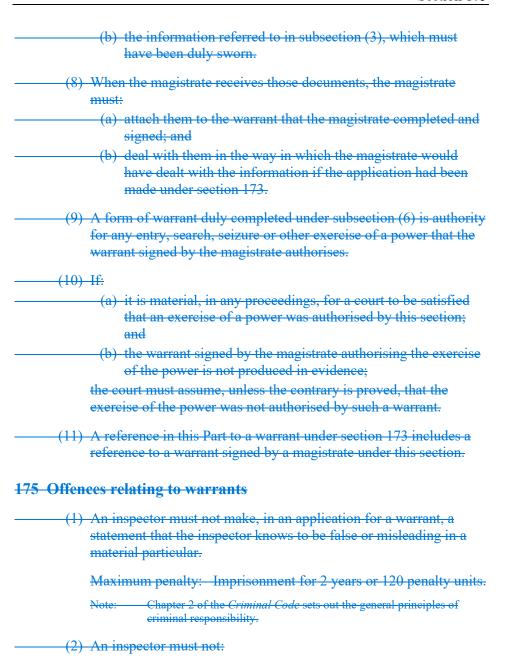
Part 11 Powers of inspection
Division 10 Warrants

Section 174



Powers of inspection Part 11
Warrants Division 10

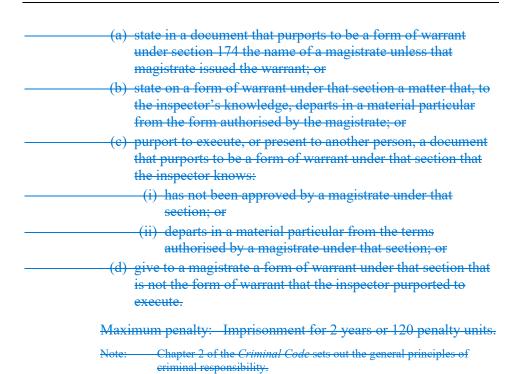
Section 175



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Part 11 Powers of inspection Division 10 Warrants





Powers of inspection Part 11
Other matters Division 11

Section 176

Division 11—Other matters

176 Part not to abrogate privilege against self-incrimination

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

177 Part does not limit power to impose conditions

This Part is not to be taken to limit the Regulator's power to impose licence conditions or the Minister's power to impose conditions on an emergency dealing determination.

Gene Technology Act 2000

Part 12 MiscellaneousDivision 1 Simplified outline

Section 178

Part 12—Miscellaneous

Division 1—Simplified outline

178 Simplified outline

The following is a simplified outline of this Part:

This Part provides for miscellaneous matters, including the following:

- (a) review of decisions;
- (aa) matters relating to applications;
- (b) provisions relating to <u>confidentiality and information</u> <u>sharing-confidential commercial information</u>;
- (c) the making of regulations and rules;
- (d) transitional provisions;
- (e) review of the operation of the Act.

Miscellaneous Part 12
Matters relating to applications Division 1A

Section 178A

Division 1A—Matters relating to applications

178A Applications to which this Division applies

This Division applies in relation to an application that is made under any of the following:

- (a) section 40 (application for GMO licence);
- (b) section 40A (application for GMO licence—inadvertent dealings);
 - (c) section 70 (application for transfer of GMO licence);
- (d) section 71A (application for variation of GMO licence);
 - (e) section 72AC (application for GMO permit);
 - (f) paragraph 78(2)(a) (application for determination for dealing to be included on GMO Register);
 - (g) section 83 (application for certification);
 - (h) section 87A (application for variation of certification);
 - (i) section 89A (application for transfer of certification);
 - (j) section 91 (application for accreditation);
 - (k) section 95A (application for variation of accreditation);
 - (1) section 187 (application for non-disclosure of CCI).

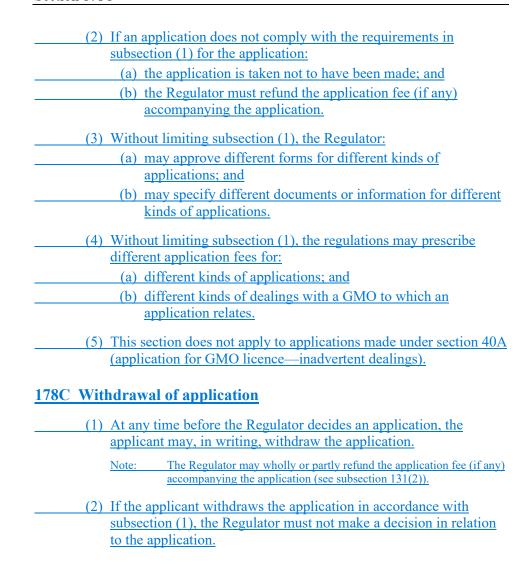
178B Requirements for applications

- (1) An application must:
 - (a) be made in the manner approved by the Regulator; and
 - (b) be in the form approved by the Regulator; and
 - (c) be accompanied by any documents or information specified in writing by the Regulator; and
 - (d) subject to subsection (2), be accompanied by the application fee (if any):
 - (i) prescribed by the regulations for the purposes of this paragraph; or
 - (ii) worked out in accordance with a method prescribed by the regulations for the purposes of this paragraph.

Gene Technology Act 2000

Part 12 MiscellaneousDivision 1A Matters relating to applications

Section 178C



178D Regulator may require applicant to give further information

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

Miscellaneous Part 12
Matters relating to applications Division 1A

Section 178E (2) The notice must specify the period within which the information is to be provided. (3) The period specified must: (a) begin on the day after the notice is given to the applicant; and (b) end: (i) in the case of an application for a GMO licence under section 40 that is not an inadvertent dealings application—at least 20 business days after that day; or (ii) otherwise—at least 10 business days after that day. (4) If the applicant does not provide the required information within the period specified in the notice, the application is taken to be withdrawn. (5) If an application is taken to be withdrawn under subsection (4), the Regulator must not make a decision in relation to the application. 178E Deadlines for making reviewable decisions If the Regulator is required to make a decision in relation to an application to which this Division applies within the consideration period for the application, but does not make a decision within that period: (a) the Regulator is taken to have made a reviewable decision to refuse the application at the end of that period; and (b) the applicant may seek internal review of the reviewable decision under section 181. 178F Consideration period (1) The *consideration period* for an application referred to in column 1 of an item of the following table is: (a) the period (the *initial period*), set out in column 2 of the item, starting on the day after the Regulator receives the

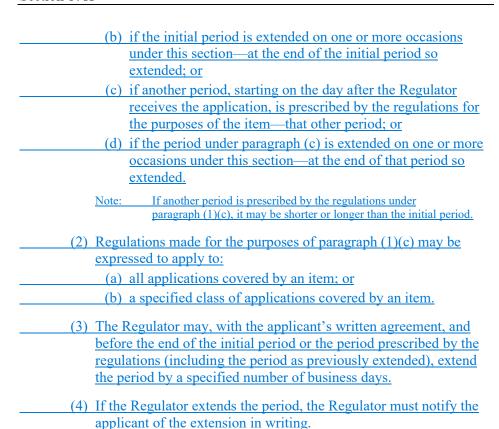
Gene Technology Act 2000

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application; or

Part 12 MiscellaneousDivision 1A Matters relating to applications

Section 178F



Initial period for applications				
<u>Item</u>	Column 1	Column 2		
	Application	Initial period		
1	Application for a GMO licence under section 40 that is not an inadvertent dealings application, if the Regulator consulted the public about the RARMP for the application under Division 4 of Part 5	200 business days		
<u>2</u>	Application for a GMO licence under section 40 that is not an	150 business days		

Miscellaneous Part 12 Matters relating to applications Division 1A

Section 178F

Initial period for applications			
Item	Column 1	Column 2	
	Application	Initial period	
	inadvertent dealings application, if the Regulator did not consult the public about the RARMP for the application under Division 4 of Part 5		
3	Application for a GMO licence under section 40 that is an inadvertent dealings application, or an inadvertent dealings application under section 40A.	90 business days	
4	Application to transfer a GMO licence under section 70	90 business days	
<u>5</u>	Application to vary a GMO licence under section 71A	90 business days	
<u>6</u>	Application for a GMO permit under section 72AC	30 business days	
7	Application for a determination for a GMO dealing to be included on the GMO Register under paragraph 78(2)(a)	200 business days	
8	Application for certification under section 83	90 business days	
9	Application for variation of certification under section 87A	90 business days	
<u>10</u>	Application for transfer of certification under section 89A	90 business days	
11	Application for accreditation under section 91	90 business days	
<u>12</u>	Application for variation of an accreditation under section 95A	90 business days	
<u>13</u>	Application for non-disclosure of CCI under section 187	40 business days	

Gene Technology Act 2000

Part 12 MiscellaneousDivision 1A Matters relating to applications

Section 178F

(5) If a circumstance mentioned in column 1 of an item in the following table applies in relation to an application, then for the purposes of calculating the consideration period for the application, exclude the period beginning on the day mentioned in column 2 of the item and ending on the day mentioned in column 3 of the item.

Calculating excluded periods			
<u>Item</u>	Column 1	Column 2	Column 3
	If this circumstance applies:	exclude the period beginning on:	and ending on:
1	the applicant is given a notice under section 178D requiring the applicant to provide further information in relation to the application	the day after the notice is given to the applicant	the day after the applicant provides the further information to the Regulator.
2	a person is given a notice under section 186 of a proposed public disclosure of CCI	the day after the notice is given to the person	if: (a) the person does not make an application under section 187—the day the period specified in the notice under section 186 expires; or (b) the Regulator makes a decision under subparagraph 187A(1)(b)(ii)—the day the decision is made; or (c) the Regulator makes a decision under paragraph 187A(1)(a) or subparagraph 187A(1)(b)(ii)—the day any review

Miscellaneous Part 12 Matters relating to applications Division 1A

Section 178F

Calculating excluded periods			
<u>Item</u>	Column 1	Column 2	Column 3
	If this circumstance applies:	exclude the period beginning on:	and ending on:
			rights under Division 2 of this Part in relation to the decision have been exhausted or have expired.
<u>3</u>	a circumstance prescribed by the regulations	a day prescribed by the regulations	a day prescribed by the regulations.

(6) For the purposes of calculating the total number of days to be excluded from a consideration period for an application under subsection (5), if a day in a period to be excluded under an item in the table in that subsection overlaps with a day in another period calculated for the same or a different item, that day must only be counted once.

Gene Technology Act 2000

Part 12 Miscellaneous

Division 2 Review of decisions

Section 179

Division 2—Review of decisions

179 Meaning of terms

The following table sets out:

- (a) decisions that are reviewable decisions; and
- (b) each *eligible person* in relation to a reviewable decision:

Reviev	Reviewable decisions and eligible persons			
Item	Decision	Provision under which decision made	Eligible person in relation to decision	
1A	To refuse to consider an application on the basis that the applicant is not a suitable person to hold a GMO licencea licence	paragraph 43(2)(f)	the applicant for the licence	
<u>1B</u>	To issue a GMO licence	section 55	the applicant for the licence	
1	To refuse to issue <u>a</u> <u>GMO licence</u> <u>a licence</u>	section 55	the applicant for the licence	
2	To impose <u>a GMO</u> <u>licence</u> <u>a licence</u> condition	section 55	the licence holder	
3	To suspend or cancel <u>a</u> <u>GMO licence</u> <u>a licence</u>	section 68	the licence holder	
3A	To refuse to transfer a GMO licence licence	section 70	an applicant for the transfer	
4	To vary <u>a GMO</u> <u>licence</u> <u>licence</u>	section 71	the licence holder	
4 A	To refuse to vary a licence	section 71	the licence holder	
<u>4A</u>	To vary a GMO licence	section 71A	the licence holder	
<u>4B</u>	To refuse to vary a GMO licence	section 71A	the licence holder	

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Miscellaneous Part 12
Review of decisions Division 2

Section 179

Reviewable decisions and eligible persons			
Item	Decision	Provision under which decision made	Eligible person in relation to decision
<u>4C</u>	To issue a GMO permit	section 72AD	the applicant for the permit
<u>4D</u>	To refuse to issue a GMO permit	section 72AD	the applicant for the permit
<u>4E</u>	To suspend or cancel a GMO permit	section 72AG	the permit holder
5	To refuse to certify a facility to a particular containment level To refuse to certify a facility	section 84	the applicant for certification
6	To imposespecify a condition of a certification	section 86	the holder of the certification
7	To vary a certification	section 87	the holder of the certification
<u>7AA</u> <u>A</u>	To vary a certification	section 87A	the holder of the certification
<u>7AA</u>	To refuse to vary a certification	section 87A	the holder of the certification
7A	To refuse to transfer a certification	section 89A	an applicant for the transfer
8	To suspend or cancel a certification	section 88	the holder of the certification
<u>8A</u>	To refuse to suspend a certification	section 88	the holder of the certification
9	To refuse to accredit an organisation	section 92	the applicant for accreditation
10	To imposespecify a condition of an accreditation	section 94	the holder of the accreditation

Gene Technology Act 2000

Part 12 Miscellaneous

Division 2 Review of decisions

Section 180

Review	Reviewable decisions and eligible persons			
Item	Decision	Provision under which decision made	Eligible person in relation to decision	
11	To vary an accreditation	section 95	the holder of the accreditation	
<u>11A</u>	To vary an accreditation	section 95A	the holder of the accreditation	
<u>11B</u>	To refuse to vary an accreditation	section 95A	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	
<u>13</u>	To give directions if a GMO licence or GMO permit is not, or will not be, in force	subsection 167(4)	the licence holder, permit holder or former licence or permit holder (as the case requires)	
<u>14</u>	To decide information subject to a publication requirement is not CCI	paragraph 187A(1)(a)	the applicant for the non-disclosure of CCI	
<u>15</u>	To publicly disclose CCI	subparagraph 187A(1)(b)(i)	the applicant for the non-disclosure of CCI	

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:

Miscellaneous Part 12
Review of decisions Division 2

Section 181

- (a) the terms of the decision; and
- (b) the reasons for the decision; and
- (c) a statement setting out particulars of the person's review rights.
- (2) A failure to comply with the requirements of subsection (1) in relation to a decision does not affect the validity of the decision.

181 Internal review

- (1) An eligible person in relation to a reviewable decision (other than a decision made by the Regulator personally) may apply in writing to the Regulator for review (*internal review*) of the decision.
- (2) An application for internal review must be made within <u>20</u> business days after the day the notice of the decision is given to the eligible person 30 days after the day on which the decision first came to the notice of the applicant, or within such period (if any) as the Regulator, either before or after the end of that period, allows.
- (3) The Regulator must, on receiving an application, review the reviewable decision personally.
- (4) The Regulator may:
 - (a) make a decision affirming, varying or revoking the reviewable decision; and
 - (b) if the Regulator revokes the decision, make such other decision as the Regulator thinks appropriate.
- (5) If the Regulator does not review the reviewable decision within a period of 60 business days beginning on the day the application is received, the Regulator is taken to have affirmed the decision.

(a) this Act provides for a person to make an application of any kind to the Regulator; and

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Part 12 Miscellaneous

Division 2 Review of decisions

Section 183

- (b) a 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;

the Regulator is taken, for the purposes of this Act, to have made a reviewable decision to reject the application, and the person may seek internal review of the reviewable decision under section 181.

183 Review of decisions by Administrative Appeals Tribunal

- (1) Subject to the *Administrative Appeals Tribunal Act 1975*, an application may be made by an eligible person in relation to:
 - (a) a reviewable decision made by the Regulator personally; or
 - (b) a decision made by the Regulator under section 181 (which provides for internal review).
- (2) In this section:

decision has the same meaning as in the *Administrative Appeals Tribunal Act 1975*.

183A Extended standing for judicial review

- (1) This section extends (and does not limit) the meaning of the term *person aggrieved* in the *Administrative Decisions (Judicial Review) Act 1977* for the purposes of the application of that Act in relation to:
 - (a) a decision made under this Act or the regulations; or
 - (b) a failure to make a decision under this Act or the regulations; or
 - (c) conduct engaged in for the purpose of making a decision under this Act or the regulations.
- (2) A State is taken to be a person aggrieved by the decision, failure or conduct.

Miscellaneous Part 12
Review of decisions Division 2

Section 183A

(3) A term (except *person aggrieved*) used in this section and in the *Administrative Decisions (Judicial Review) Act 1977* has the same meaning in this section as it has in that Act.

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Part 12 Miscellaneous

Division 3 Confidentiality and information sharing

Section 184

Division 3—Confidentiality and information sharing

Subdivision A—Regulator information subject to a publication requirement

184 Regulator information subject to a publication requirement

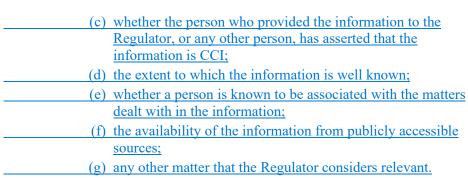
- (1) Regulator information is *subject to a publication requirement* if the Regulator is required, or proposes, to publicly disclose the information in the course of exercising the Regulator's powers or functions under this Act or a legislative instrument made under this Act.
 - Example: The Regulator may be required, or may decide, to publicly disclose Regulator information in a RARMP under section 49.
- (2) To avoid doubt, Regulator information may be subject to a publication requirement regardless of whether the information was subject to a publication requirement at any time in the past.
- (3) Despite subsection (1), the rules may specify Regulator information, or a class of Regulator information, that is not subject to a publication requirement.

185 Threshold consideration regarding public disclosure of CCI

- (1) If Regulator information is subject to a publication requirement, the Regulator must, before publicly disclosing the information, consider whether a person might reasonably wish to make an application under section 187 (person may apply for non-disclosure of CCI).
- (2) In considering the matter in subsection (1), the Regulator must have regard to the following:
 - (a) the nature of the information;
 - (b) whether the information was provided to the Regulator:
 - (i) in connection with an application made to the Regulator under this Act; or
 - (ii) in compliance or purported compliance with this Act;

Miscellaneous Part 12 Confidentiality and information sharing Division 3

Section 186



186 Notice of proposed public disclosure

- (1) If the Regulator considers that a person might reasonably wish to make an application under section 187 (person may apply for non-disclosure of CCI), the Regulator must give the person written notice of the following:
 - (a) that the Regulator proposes to publicly disclose the information and the form in which the Regulator proposes to disclose it;
 - (b) if the Regulator proposes to publicly disclose the information under a provision of this Act or a legislative instrument made under this Act—the provision;
 - (c) that the person may, within the period specified in the notice, make an application under section 187;
 - (d) that if no application is made within that period, the Regulator must or may (as the case requires) publicly disclose the information.
- (2) The period in paragraph (1)(c) must not end earlier than 10 business days after the day the notice is given.

187 Person may apply for non-disclosure of CCI

A person may apply to the Regulator:

(a) to claim that Regulator information the subject of a notice under section 186 is CCI (including CCI relating to the location of field trial sites); and

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Part 12 Miscellaneous

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Section 187A (b) for the information not to be publicly disclosed as proposed. Division 1A of Part 12 sets out requirements for applications. 187A Decision on application for non-disclosure of CCI (1) If a person makes an application under section 187, the Regulator must, within the consideration period for the application, decide: (a) the information is not CCI; or (b) the information is CCI; and (i) to publicly disclose the CCI as proposed; or (ii) not to publicly disclose the CCI as proposed. See section 178F for the consideration period for the application. A decision that the information is not CCI, and a decision to publicly Note 2: disclose CCI as proposed, are reviewable decisions (see section 179), and the Regulator must give the applicant written notice of the decision (see section 180). (2) In making a decision under subsection (1), the Regulator must take into account any information provided in the application for non-disclosure. (3) The Regulator must decide not to publicly disclose the CCI as proposed if: (a) the CCI relates to a location at which a field trial involving a GMO is occurring, or is proposed to occur; and (b) the Regulator is satisfied that the disclosure of the CCI would be likely to cause significant damage to: (i) the health and safety of people; or (ii) the environment; or (iii) property. (4) If the CCI does not relate to a location at which a field trial involving a GMO is occurring, or is proposed to occur, the Regulator may decide to publicly disclose the CCI as proposed only if the Regulator is satisfied that the public interest in the

disclosure outweighs any prejudice that the disclosure would cause

to the person.

Miscellaneous Part 12 Confidentiality and information sharing Division 3

Section 187B

(5) If the Regulator decides not to publicly disclose CCI, the Regulator must, within 14 days after making the decision, give the applicant written notice of the decision.

187B Publication of Regulator information subject to a publication requirement

- (1) The Regulator may publicly disclose Regulator information subject to a publication requirement if:
 - (a) the Regulator considered, under section 185, that no one might reasonably wish to make an application under section 187; or
 - (b) the Regulator considered, under section 185, that a person might reasonably wish to make an application under section 187 and:
 - (i) the Regulator has given a notice to the person under subsection 186; and
 - (ii) subsection (2) applies in relation to the information.
 - (2) This subsection applies if:
 - (a) no application in relation to the information has been made under subsection 187(1) within the period specified in the notice given under section 186; or
 - (b) an application was made under subsection 187(1) but withdrawn before the Regulator made a decision in relation to the application; or
 - (c) the Regulator made a decision under section 187A:
 - (i) that the information is not CCI; or
 - (ii) that the information is CCI and to publicly disclose the CCI; and

any review rights under Division 2 of this Part in relation to the decision have been exhausted or have expired.

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Part 12 Miscellaneous

Division 3 Confidentiality and information sharing

Section 187C

Subdivision B—Use and disclosure of Regulator information

187C Use and disclosure of Regulator information—entrusted persons

An entrusted person may use or disclose Regulator information only if the use or disclosure is permitted under this Division.

Note: Section 122.4 of the *Criminal Code* creates an offence in relation to the disclosure of information by Commonwealth officers etc.

187D Permitted uses and disclosures of Regulator information that is not CCI—entrusted persons

- (1) An entrusted person may use or disclose Regulator information that is not CCI if:
 - (a) the use or disclosure is made for the purposes of performing a duty or function, or exercising a power, under or in relation to this Act or a legislative instrument made under this Act; and
 - (b) the use or disclosure is not contrary to Australia's obligations under international law, including obligations under any agreement between Australia and another country or other countries; and
 - (c) in relation to use—where:
 - (i) the entrusted person uses the information for the purpose of granting a GMO licence to an applicant who is not the person from whom the information was obtained; and
 - (ii) the information relates to the affairs of another person (the *other person*); and
 - (iii) the entrusted person would be otherwise unable to grant the licence due to insufficient information from the applicant;

the other person (or person duly authorised on their behalf) has consented to that use of the information for that purpose; and

Miscellaneous Part 12 Confidentiality and information sharing Division 3

Section 187D (d) in relation to disclosure—the disclosure is not a disclosure of personal information (within the meaning of the *Privacy Act* 1988). (2) An entrusted person may use or disclose Regulator information that is not CCI if the use or disclosure is required or authorised by or under: (a) a Commonwealth law (including this Act); or (b) a law of a State. (3) An entrusted person may use or disclose Regulator information that is not CCI if the information is an individual's personal information (within the meaning of the Privacy Act 1988) and the individual has consented to the use or disclosure. (4) An entrusted person may disclose Regulator information that is not CCI to a Commonwealth agency, a Commonwealth authority, a State agency or the Gene Technology Technical Advisory Committee if: (a) the disclosure is made for the purposes of enabling the authority, agency or Committee to perform a duty or function, or exercise a power, under or in relation to this Act or a legislative instrument made under this Act; and (b) the disclosure is not contrary to Australia's obligations under international law, including obligations under any agreement between Australia and another country or other countries. (5) An entrusted person may disclose Regulator information that is not CCI to a Commonwealth agency, a Commonwealth authority, a State agency or an entity prescribed by the regulations if: (a) the disclosure is made for the purposes of enabling or assisting the authority, agency or entity to perform its duties or functions, or exercise its powers; and (b) the disclosure is not contrary to Australia's obligations under international law, including obligations under any agreement between Australia and another country or other countries.

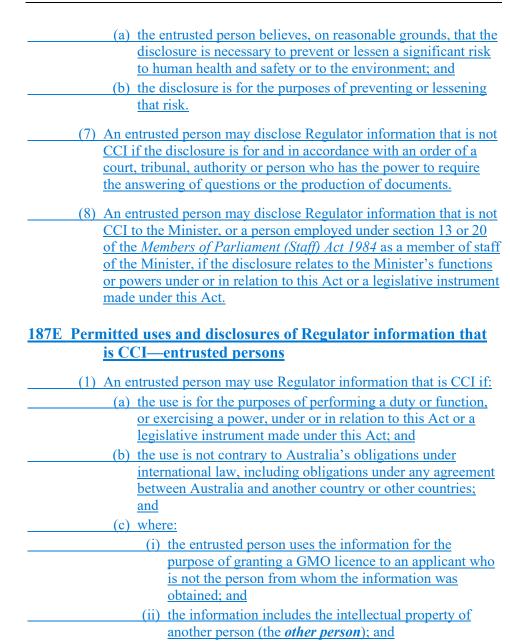
Gene Technology Act 2000

(6) An entrusted person may disclose Regulator information that is not

CCI if:

Part 12 MiscellaneousDivision 3 Confidentiality and information sharing

Section 187E



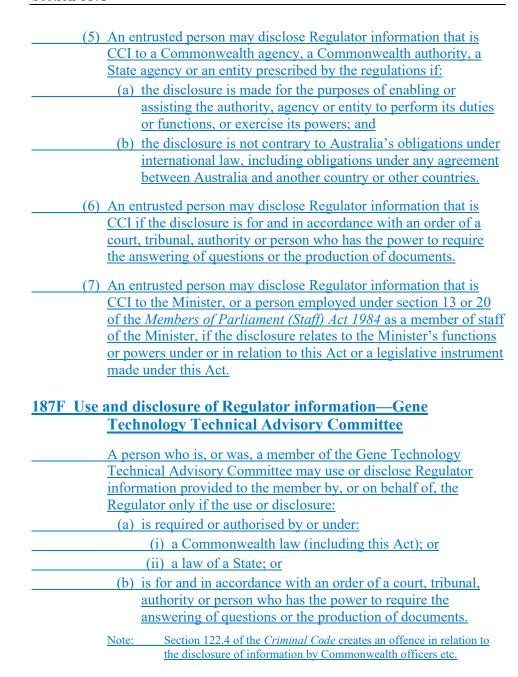
Miscellaneous Part 12 Confidentiality and information sharing Division 3

Section 187E (iii) the entrusted person would be otherwise unable to grant the licence due to insufficient information from the applicant; the other person (or person duly authorised on their behalf) has consented to that use of the information for that purpose. (2) An entrusted person may use or disclose Regulator information that is CCI if the use or disclosure is required or authorised by or under: (a) a Commonwealth law (including this Act); or (b) a law of a State. Note: See Subdivision A of this Division in relation to when the Regulator may publicly disclose information subject to a publication requirement. (3) An entrusted person may disclose Regulator information that is CCI if: (a) the disclosure is for the purposes of performing a duty or function, or exercising a power, under or in relation to this Act or a legislative instrument made under this Act; and (b) both of the following apply: (i) the information is the intellectual property of a person; (ii) the person (or person duly authorised on their behalf) has consented to the disclosure. (4) An entrusted person may disclose Regulator information that is CCI to a Commonwealth agency, a Commonwealth authority, a State agency or the Gene Technology Advisory Committee if: (a) the disclosure is made for the purposes of enabling the authority, agency or Committee to perform a duty or function, or exercise a power, under or in relation to this Act, or a legislative instrument made under this Act; and (b) the disclosure is not contrary to Australia's obligations under international law, including obligations under any agreement between Australia and another country or other countries.

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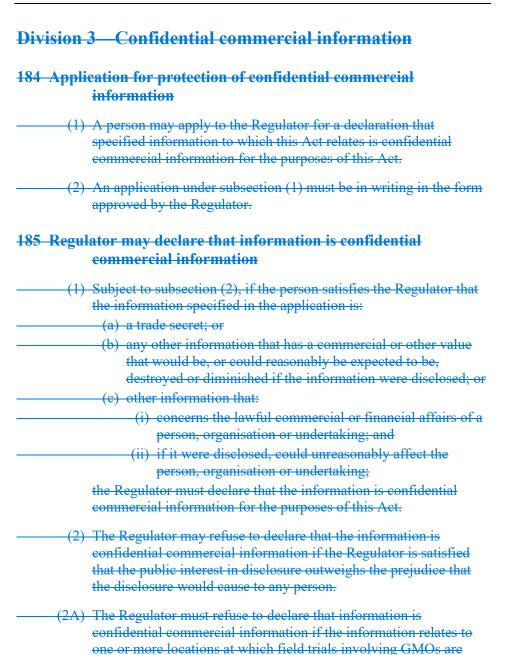
Part 12 MiscellaneousDivision 3 Confidentiality and information sharing

Section 187F



Miscellaneous Part 12 Confidential commercial information Division 3

Section 184



Gene Technology Act 2000

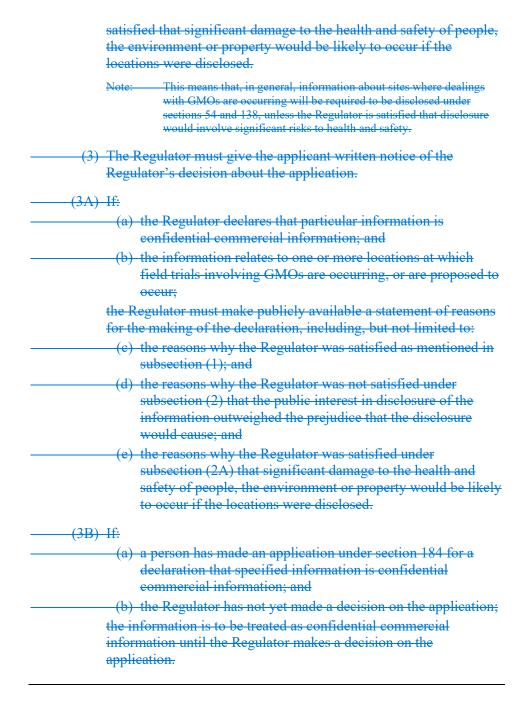
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occurring, or are proposed to occur, unless the Regulator is

Part 12 Miscellaneous

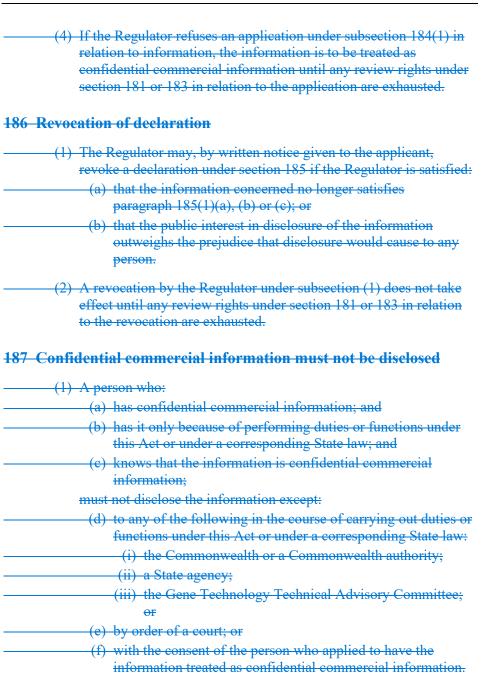
Division 3 Confidential commercial information

Section 185



Miscellaneous Part 12 Confidential commercial information Division 3

Section 186

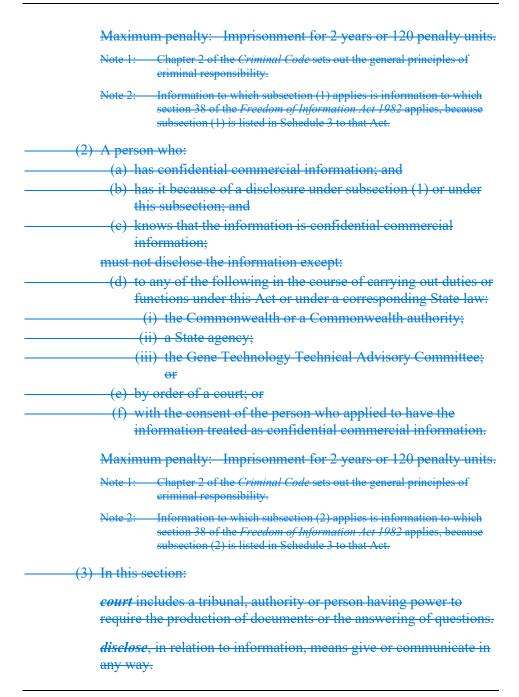


Gene Technology Act 2000

Part 12 Miscellaneous

Division 3 Confidential commercial information

Section 187



Miscellaneous Part 12 Conduct by directors, employees and agents Division 4

Section 188

Division 4—Conduct by directors, employees and agents

188 Conduct by directors, employees and agents

- (1) If, in proceedings for an offence against this Act or the regulations, or an ancillary offence in relation to this Act or the regulations, it is necessary to establish the state of mind of a body corporate in relation to particular conduct, it is sufficient to show:
 - (a) that the conduct was engaged in by a director, employee or agent of the body corporate within the scope of his or her actual or apparent authority; and
 - (b) that the director, employee or agent had the state of mind.
- (2) Any conduct engaged in on behalf of a body corporate by a director, employee or agent of the body corporate within the scope of his or her actual or apparent authority is taken, for the purposes of a prosecution for:
 - (a) an offence against this Act-or the regulations; or
 - (b) an ancillary offence relating to this Act or the regulations; to have been engaged in also by the body corporate, unless the body corporate establishes that the body corporate took reasonable precautions and exercised due diligence to avoid the conduct.
- (3) If, in proceedings for an ancillary offence relating to this Act-or the regulations, it is necessary to establish the state of mind of a person other than a body corporate in relation to particular conduct, it is sufficient to show:
 - (a) that the conduct was engaged in by an employee or agent of the person within the scope of his or her actual or apparent authority; 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

Part 12 Miscellaneous

Division 4 Conduct by directors, employees and agents

Section 189

(b) an ancillary offence relating to this Act-or the regulations; to have been engaged in also by the first person unless the first person establishes that he or she took reasonable precautions and exercised due diligence to avoid the conduct.

(5) If:

- (a) a person other than a body corporate is convicted of an offence; and
- (b) the person would not have been convicted of the offence if subsections (3) and (4) had not been enacted;

the person is not liable to be punished by imprisonment for that offence.

189 Meaning of terms

- (1) A reference in subsection 188(1) or (3) to the state of mind of a person includes a reference to:
 - (a) the knowledge, intention, opinion, belief or purpose of the person; 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 or under a law of the Commonwealth or a State.
- (3) A reference in section 188 to engaging in conduct includes a reference to failing or refusing to engage in conduct.
- (4) A reference in section 188 to an ancillary offence relating to this Act-or the regulations is a reference to an offence:
 - (a) against section 6 of the Crimes Act 1914; or
 - (b) that is taken to have been committed because of section 11.2 or 11.2A of the *Criminal Code*; or
 - (c) against section 11.1, 11.4 or 11.5 of the *Criminal Code*; that relates to this Act-or the regulations.

Miscellaneous Part 12 Application, savings and transitional provisions Division 5

Section 189

<u>Division 5—Application, savings and transitional</u> <u>provisions</u>

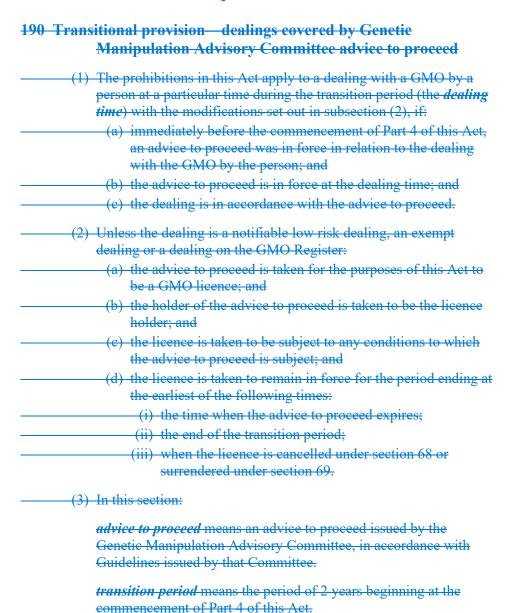
[Placeholder for new Division 5]

Part 12 Miscellaneous

Division 5 Transitional provisions

Section 190

Division 5—Transitional provisions



Miscellaneous Part 12
Transitional provisions Division 5

Section 191

191 Regulations may relate to transitional matters

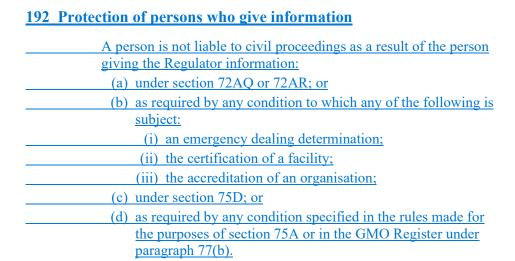
Regulations may be made in relation to transitional matters arising from the enactment of this Act.

Gene Technology Act 2000

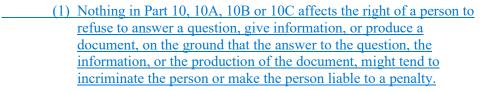
Part 12 Miscellaneous Division 6 Other

Section 192

Division 6—Other



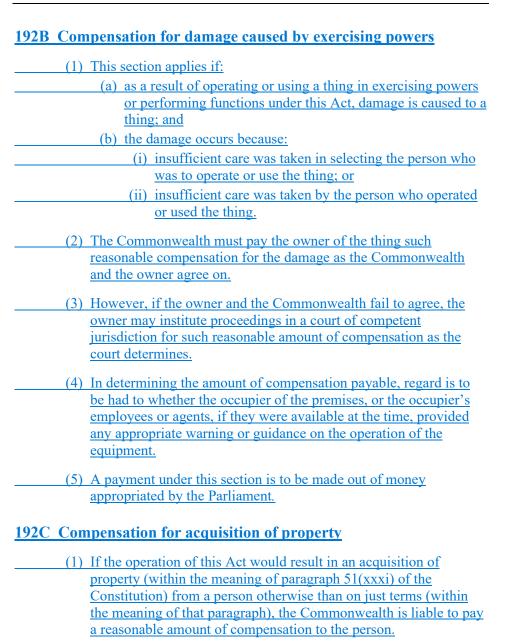
192A Privilege against self-incrimination and legal professional privilege not abrogated



- (2) Nothing in Part 10, 10A, 10B or 10C affects the right of a person to refuse to answer a question, give information, or produce a document, on the ground that:
 - (a) the answer to the question or the information would be privileged from being given on the ground of legal professional privilege; or
 - (b) the document would be privileged from being produced on the ground of legal professional privilege.

Miscellaneous Part 12
Other Division 6

Section 192B



Part 12 Miscellaneous Division 6 Other

Section 192D

(2) If the Commonwealth and the person do not agree on the amount of the compensation, the person may institute proceedings in a court of competent jurisdiction for the recovery from the Commonwealth of such reasonable amount of compensation as the court determines.

192D Immunity from civil proceedings

A person is not liable to civil proceedings in relation to an act done, or omitted to be done:

- (a) in good faith in the performance or purported performance of a function, or the exercise or purported exercise of a power, conferred on the person by this Act or the regulations; or
- (b) in good faith:
 - (i) in providing or purporting to provide assistance to the Regulator; and
 - (ii) as the result of a request, direction or other requirement made of the person by the Regulator in the performance or purported performance of a function, or the exercise or purported exercise of a power, conferred on the Regulator by this Act or the regulations.

192 False or misleading information or document

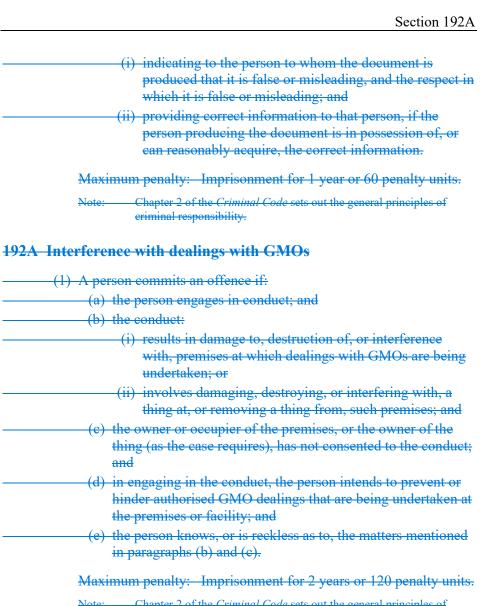
A person must not:

- (a) in connection with an application made to the Regulator under this Act or the regulations; or
 - (b) in compliance or purported compliance with this Act or the regulations;

do either of the following:

- (c) give information (whether orally or in writing) that the person knows to be false or misleading in a material particular;
 - (d) produce a document that the person knows to be false or misleading in a material particular without:

Miscellaneous Part 12
Other Division 6



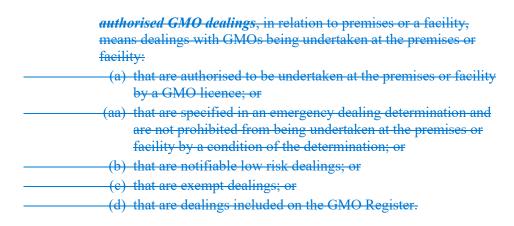
Note: Chapter 2 of the Criminal Code sets out the general principles of criminal responsibility.

(2) In this section:

Gene Technology Act 2000

Part 12 Miscellaneous Division 6 Other

Section 193



193 Regulations

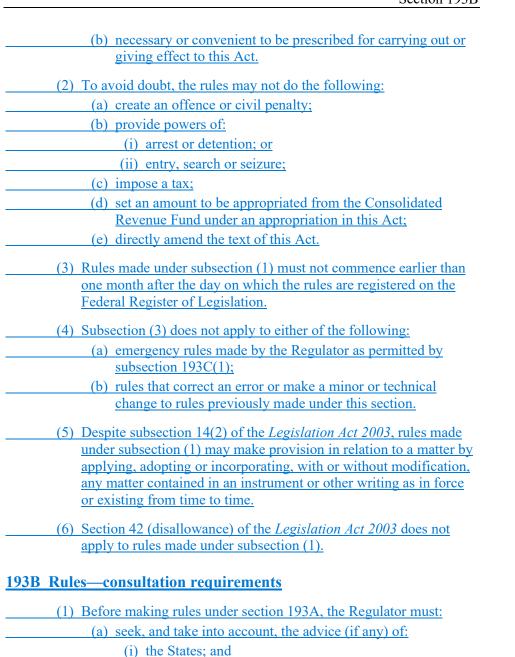
- (1) The Governor-General may make regulations prescribing matters:
 - (a) required or permitted by this Act to be prescribed; or
 - (b) necessary or convenient to be prescribed for carrying out or giving effect to this Act.
- (2) Without limiting subsection (1), the regulations may require a person to comply with <u>technical and procedural guidance</u> eodes of <u>practice or guidelines</u> issued under this Act as in force at a particular time or from time to time.
- (3) Despite subsection 14(2) of the *Legislation Act 2003*, the regulations may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

193A Rules—general

- (1) The Regulator may, by legislative instrument, make rules not inconsistent with this Act, the regulations or a policy principle in force under section 21, prescribing matters:
 - (a) required or permitted by this Act or the regulations to be prescribed by the rules; or

Miscellaneous Part 12
Other Division 6

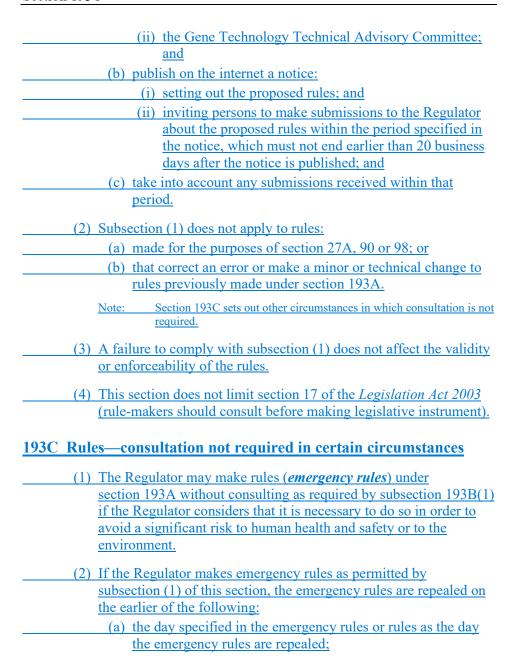
Section 193B



Gene Technology Act 2000

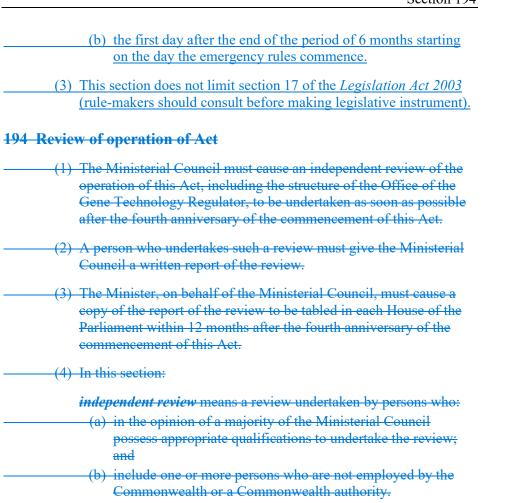
Part 12 Miscellaneous Division 6 Other

Section 193C



Miscellaneous Part 12
Other Division 6

Section 194



Gene Technology Act 2000

Endnotes

Endnote 1—About the endnotes

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes

The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment

Endnotes

Endnote 1—About the endnotes

can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to the amendment history.

Endnotes

Endnote 2—Abbreviation key

Endnote 2—Abbreviation key

ad = added or inserted o = order(s)

am = amended Ord = Ordinance

amdt = amendment orig = original

c = clause(s) par = paragraph(s)/subparagraph(s)

C[x] = Compilation No. x /sub-subparagraph(s)

disallowed = disallowed by Parliament Pt = Part(s)

 $\begin{aligned} &\text{Div} = \text{Division}(s) & & & & & & & \\ &\text{ed} = \text{editorial change} & & & & & \\ &\text{exp} = \text{expires/expired or ceases/ceased to have} & & & & \\ &\text{renum} = \text{renumbered} & & & \end{aligned}$

effect rep = repealed

F = Federal Register of Legislation rs = repealed and substituted gaz = gazette s = section(s)/subsection(s)

LA = Legislation Act 2003 Sch = Schedule(s)
LIA = Legislative Instruments Act 2003 Sdiv = Subdivision(s)

(md) = misdescribed amendment can be given SLI = Select Legislative Instrument

effect SR = Statutory Rules
(md not incorp) = misdescribed amendment Sub-Ch = Sub-Chapter(s)

cannot be given effect SubPt = Subpart(s)

mod = modified/modification underlining = whole or part not No. = Number(s) commenced or to be commenced

Endnotes

Endnote 3—Legislation history

Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Gene Technology Act 2000	169, 2000	21 Dec 2000	s 1 and 2: 21 Dec 2000 (s 2(1)) s 10, 26, 27(b)–(1), 28–30, 120, 121, 129, 130 and 132–135: 20 Apr 2001 (Gazette 2001, No S140) Remainder: 22 June 2001	
Australia New Zealand Food Authority Amendment Act 2001	81, 2001	10 July 2001	Sch 3 (item 2): 1 July 2002 (s 2(5)(b) and <i>gaz</i> 2002, No GN30)	_
Prohibition of Human Cloning Act 2002	144, 2002	19 Dec 2002	s 3–26 and Sch 1: 16 Jan 2003 (s 2(1) item 2) Remainder: 19 Dec 2002 (s 2(1) item 1)	_
Financial Framework Legislation Amendment Act (No. 1) 2006	30, 2006	6 Apr 2006	Sch 1 (items 25–28): 7 Apr 2006	_
Gene Technology Amendment Act 2007	99, 2007	28 June 2007	Sch 1 (items 1–23, 36–61) and Sch 2: 1 July 2007 (s 2(1) items 2, 4, 5) Sch 1 (items 24–35): 1 Jan 2008 (s 2(1) item 3) Remainder: 28 June 2007 (s 2(1) item 1)	Sch 1 (item 35)
Superannuation Legislation Amendment (Trustee Board and Other Measures) (Consequential Amendments) Act 2008	26, 2008	23 June 2008	Sch 1 (items 73–76): 23 June 2008 (s 2(1) item 4)	_

Gene Technology Act 2000

Endnotes

Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Crimes Legislation Amendment (Serious and Organised Crime) Act (No. 2) 2010	4, 2010	19 Feb 2010	Sch 11 (item 11): 20 Feb 2010	_
Acts Interpretation Amendment Act 2011	46, 2011	27 June 2011	Sch 2 (items 650–652) and Sch 3 (items 10, 11): 27 Dec 2011	Sch 3 (items 10, 11)
Superannuation Legislation (Consequential Amendments and Transitional Provisions) Act 2011	58, 2011	28 June 2011	Sch 1 (items 90–93): 1 July 2011 (s 2(1) item 2)	_
Public Governance, Performance and Accountability (Consequential and Transitional Provisions) Act 2014	62, 2014	30 June 2014	Sch 9 (items 119–122) and Sch 14: 1 July 2014 (s 2(1) items 6, 14)	Sch 14

Endnotes

Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
as amended by				
Public Governance and Resources Legislation Amendment Act (No. 1) 2015	36, 2015	13 Apr 2015	Sch 2 (items 7–9) and Sch 7: 14 Apr 2015 (s 2)	Sch 7
as amended by				
Acts and Instruments (Framework Reform) (Consequential Provisions) Act 2015	126, 2015	10 Sept 2015	Sch 1 (item 486): 5 Mar 2016 (s 2(1) item 2)	_
Acts and Instruments (Framework Reform) (Consequential Provisions) Act 2015	126, 2015	10 Sept 2015	Sch 1 (item 495): 5 Mar 2016 (s 2(1) item 2)	_
Acts and Instruments (Framework Reform) Act 2015	10, 2015	5 Mar 2015	Sch 3 (items 152–159, 348, 349): 5 Mar 2016 (s 2(1) item 2)	Sch 3 (items 348, 349)
Gene Technology Amendment Act 2015	121, 2015	10 Sept 2015	Sch 1: 10 Mar 2016 (s 2(1) item 2)	Sch 1 (items 3, 6, 19, 21)
Statute Law Revision Act (No. 1) 2016	4, 2016	11 Feb 2016	Sch 4 (items, 1, 178): 10 Mar 2016 (s 2(1) item 6)	_
Territories Legislation Amendment Act 2016	33, 2016	23 Mar 2016	Sch 5 (item 59): 1 July 2016 (s 2(1) item 7)	_

Gene Technology Act 2000

Endnotes

Endnote 4—Amendment history

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
s 7	am No. 33, 2016
s 8	am No 4, 2016
Part 2	
Division 2	
s. 10	am. No. 99, 2007; No. 58, 2011; No 121, 2015
Division 4	
Subdivision A	
s. 17	am. No. 99, 2007; No 121, 2015
Subdivision B	
s 21	am No 10, 2015
s. 22	am. No. 99, 2007
s. 24	am. No. 99, 2007; No 10, 2015
Part 3	
s 30	am No 121, 2015
Part 4	
Division 1	
s. 31	am. No. 99, 2007
Division 2	
s. 32	am. No. 99, 2007; No 4, 2016
s. 33	am. No. 99, 2007; No 4, 2016
s. 34	am. No. 99, 2007; No 4, 2016
s 35	am No 4, 2016
s. 35A	ad. No. 99, 2007
	am No 4, 2016
s. 35B	ad No 99, 2007
	am No 4, 2016
s 36	am No 4, 2016
s 37	am No 4, 2016

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Endnotes

Endnote 4—Amendment history

Provision affected	How affected
Part 5	
Division 2	
s. 40A	ad. No. 99, 2007
ss. 42, 43	am. No. 99, 2007
Division 3	
s. 46A	ad. No. 99, 2007
	am No 121, 2015
Division 4	
s. 49	rs. No. 99, 2007
	am No 121, 2015
s. 50	am. No. 99, 2007
s. 50A	ad. No. 99, 2007
s. 51	am. No. 99, 2007
s. 52	am. No. 99, 2007; No 121, 2015
Division 5	
s. 56	am. No. 99, 2007
Note to s. 56	ad. No. 99, 2007
s. 57	am. No. 99, 2007
s. 60	am. No. 99, 2007
Division 6	
s. 67	am. No. 99, 2007
Division 7	
s 71	am. No. 99, 2007; No 121, 2015
s 72	am No 99, 2007
Part 5A	
Part 5A	ad. No. 99, 2007
Division 1	
s. 72A	ad. No. 99, 2007
Division 2	
ss. 72B, 72C	ad. No. 99, 2007
Division 3	

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Endnote 4—Amendment history

Provision affected	How affected
s. 72D	ad. No. 99, 2007
Division 4	
s. 72E	ad. No. 99, 2007
Part 6	
Division2	
s 74	am No 121, 2015
Division 3	
s. 78	am. No. 99, 2007; No 10, 2015
Part 7	
Division 1	
s. 82	am. No. 99, 2007
Division 2	
s 80	am No 10, 2015
Note to s. 83(2)	am. No. 99, 2007
s. 89	am. No. 99, 2007
s. 89A	ad. No. 99, 2007
Division 3	
Note to s. 91(1)	rep. No. 99, 2007
Notes 1, 2 to s. 91(1)	ad. No. 99, 2007
s. 92	am. No. 99, 2007
s. 97	am. No. 99, 2007
Part 8	
Heading to Part 8	rs. No. 99, 2007
Division 1	
s. 99	am. No. 99, 2007
Division 2	
s. 100	am. No. 99, 2007
Division 3	
Div. 3 of Part 8	rs. No. 99, 2007
s. 106	rs. No. 99, 2007
s. 107	rs. No. 99, 2007

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Endnote 4—Amendment history

Provision affected	How affected	
s. 108	rs. No. 99, 2007	
s. 109	rs. No. 99, 2007	
s. 110	rs. No. 99, 2007	
s. 110A	rep. No. 99, 2007	
ss. 111, 112	rs. No. 99, 2007	
Div. 4 of Part 8	rep. No. 99, 2007	
ss. 113–116	rep. No. 99, 2007	
Part 9		
Division 1		
s 117	am No 62, 2014; No 121, 2015	
Division 2		
s. 119	am. No. 26, 2008; No. 58, 2011	
s. 121	am. No. 46, 2011	
Note to s. 121	ad. No. 46, 2011	
Division 3		
s 128	am No 62, 2014	
s 129	am No 62, 2014	
s. 130	am. No. 30, 2006	
Note to s. 130(1)	ad. No. 30, 2006	
	am No 62, 2014	
Division 5		
s 136	am No 121, 2015	
s. 136A	am. No. 99, 2007	
	rep No 121, 2015	
Division 6		
Division 6 heading	rs No 121, 2015	
s. 138	am. No. 81, 2001; No. 99, 2007; No 121, 2015	
Part 10		
s. 145	am. No. 99, 2007	
s. 146	am. No. 99, 2007	

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Endnote 4—Amendment history

Provision affected	How affected
Part 11	
Division 1	
s. 149	am. No. 99, 2007
Division 3	
s. 152	am. No. 99, 2007
Division 11	
Heading to s. 177	am. No. 99, 2007
s. 177	am. No. 99, 2007
Part 12	
Division 2	
s. 179	am. No. 99, 2007
s. 182	am. No. 99, 2007
Division 3	
s. 185	am. No. 99, 2007
Division 4	
s. 189	am. No. 4, 2010
Division 6	
s. 192A	am. No. 99, 2007; No 4, 2016
ss. 192B–192D	rep. No. 144, 2002