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# Gene Technology Regulations 2001

Statutory Rules 2001 No. 1

106

I, WILLIAM PATRICK DEANE, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Gene Technology Act 2000*.

Dated 30 MAY 2001 2001

**WILLIAM DEANE**  
Governor-General

By His Excellency's Command

MICHAEL WOOLDRIDGE  
Minister for Health and Aged Care

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**Contents**

	Page
<b>Part 1</b>	<b>Preliminary</b>
1	Name of Regulations 5
2	Commencement 5
3	Definitions 5
<b>Part 2</b>	<b>Interpretation and general operation</b>
4	Techniques not constituting gene technology 7
5	Organisms that are not genetically modified organisms 7
<b>Part 3</b>	<b>Dealings with GMOs</b>
<b>Division 1</b>	<b>Licensing system</b>
6	Dealings exempt from licensing 8
7	Application for licence — prescribed information 8
8	Time limit for deciding an application 9
9	Prescribed authorities 11
10	Risk assessment — matters to be taken into account 11
11	Prescribed conditions of licence 12
<b>Division 2</b>	<b>Notifiable low risk dealings</b>
12	Notifiable low risk dealings 12
13	Requirements in relation to notifiable low risk dealings 12
<b>Division 3</b>	<b>Certification and accreditation</b>
14	Regulator to decide certification application within 90 days 14
15	Application for certification — failure to provide section 85 information 14
16	Regulator to decide accreditation application within 90 days 15
17	Application for accreditation — failure to provide section 93 information 15

		Page
<b>Part 4</b>	<b>Gene Technology Technical Advisory Committee</b>	
<b>Division 1</b>	<b>Conditions of appointment</b>	
	18 GTTAC members and advisers — term of appointment	16
	19 GTTAC members and advisers — resignation	16
	20 GTTAC members — disclosure of interests	16
	21 GTTAC members and advisers — termination of appointment	17
	22 GTTAC members — leave of absence	18
	23 Expert advisers — disclosure of interests	18
<b>Division 2</b>	<b>Committee procedures</b>	
	24 Committee procedures generally	19
	25 Committee meetings	19
	26 Presiding member	20
	27 Quorum	20
	28 Voting	20
	29 Records and Reports	21
<b>Division 3</b>	<b>Subcommittees</b>	
	30 Operation of subcommittees	21
<b>Part 5</b>	<b>Gene Technology Community Consultative Committee</b>	
	31 GTCCC — conditions of appointment	22
	32 GTCCC — Consultative Committee procedures	22
	33 GTCCC — operation of subcommittees	23
<b>Part 6</b>	<b>Gene Technology Ethics Committee</b>	
	34 GTEC — Conditions of appointment	24
	35 GTEC — Committee procedures	24
	36 GTEC — operation of subcommittees	25
<b>Part 7</b>	<b>Miscellaneous</b>	
	37 Reviewable State decisions	26
	38 Review of decisions	26
	39 Record of GMO and GM Product Dealings	26

	Page
40 Inspector identity card	27
<b>Part 8</b>	<b>Transitional</b>
41 Existing facilities — certification	28
42 Existing organisations — accreditation	29
<b>Schedule 1</b>	<b>Organisms that are not genetically modified organisms</b>
Part 1	30
Part 2	31
<b>Schedule 2</b>	<b>Dealings exempt from licensing</b>
Part 1	33
Part 2	34
Part 3	36
<b>Schedule 3</b>	<b>Notifiable low risk dealings in relation to a GMO</b>
Part 1	37
Part 2	39
Part 3	40
<b>Schedule 4</b>	<b>Prescribed information — application for a licence</b>
Part 1	44
Part 2	52

## Part 1 Preliminary

### 1 Name of Regulations

These Regulations are the *Gene Technology Regulations 2001*.

### 2 Commencement

These Regulations commence on the date of commencement of provisions of the Act to which subsection 2 (3) of the Act apply.

### 3 Definitions

In these Regulations:

*Act* means the *Gene Technology Act 2000*.

*advice to proceed*, being an instrument so named issued by the Genetic Manipulation Advisory Committee, has the same meaning as in subsection 190 (3) of the Act.

*animal* includes every kind of organism in the animal kingdom, including non-vertebrates but not including human beings.

*expert adviser* means:

- (a) in Part 4 — an expert adviser appointed under subsection 102 (1) of the Act; and
- (a) in Part 6 — an expert adviser appointed under subsection 113 (1) of the Act.

*Genetic Manipulation Advisory Committee* means the Committee of that name administered by the Minister for Health and Aged Care.

*physical containment level*, followed by a numeral, is a specified containment level under guidelines made by the Regulator, under section 90 of the Act, for the certification of facilities.

### Regulation 3

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*Note* Several other words and expressions used in these Regulations have the meaning given by section 10, or another provision, of the Act. For example:

- accredited organisation
- deal with
- environment
- facility
- Gene Technology Technical Advisory Committee
- GMO
- GM product
- Institutional Biosafety Committee
- intentional release of the GMO into the environment (see section 11)
- notifiable low risk dealing
- Regulator.

## Part 2 Interpretation and general operation

### 4 Techniques not constituting gene technology

For paragraph (c) of the definition of *gene technology* in section 10 of the Act, gene technology does not include somatic cell nuclear transfer if the transfer does not involve genetically modified material.

### 5 Organisms that are not genetically modified organisms

For paragraph (e) of the definition of *genetically modified organism* in section 10 of the Act, an organism mentioned in Schedule 1 is not a genetically modified organism.

## **Part 3 Dealings with GMOs**

### **Division 1 Licensing system**

#### **6 Dealings exempt from licensing**

- (1) For subsection 32 (3) of the Act, a dealing, in relation to a GMO, is an exempt dealing if:
  - (a) it is a dealing of a kind mentioned in Part 1 of Schedule 2; and
  - (b) it does not involve a genetic modification other than a modification described in Part 1 of Schedule 2; and
  - (c) it is conducted in accordance with Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology) for physical containment Level 1; and
  - (d) it does not involve an intentional release of the GMO into the environment.
- (2) For the avoidance of doubt, exemption under subregulation (1) does not apply to a dealing that does not comply with subregulation (1), whether or not that dealing is related to a dealing that does so comply.

*Note 1* A dealing affected by this regulation could be any of the forms of dealing mentioned in the definition of *deal with* in subsection 10 (1) of the Act.

*Note 2* Exemption from provisions of the Act does not preclude the application of other Commonwealth and State laws.

#### **7 Application for licence — prescribed information**

- (1) For paragraph 40 (2) (a) of the Act, the following information must be contained in an application for a licence:
  - (a) for an application to which Division 3 of Part 5 of the Act applies — the information specified in Part 1 of Schedule 4;
  - (b) for an application to which Division 4 of Part 5 of the Act applies — the information specified in Part 2 of Schedule 4.



- (2) In preparing that information, an applicant must take account of risks that the proposed dealing, or dealings, with a GMO may incur in relation to the health and safety of people and the environment.
- (3) The information to be given in the application must be:
  - (a) as comprehensive as existing scientific knowledge, when the application is made, permits; and
  - (b) supported by whatever relevant data and references are available to the applicant.
- (4) To the extent that compliance with paragraph (3) (b) does not provide relevant data and references, the applicant must include in the application:
  - (a) a statement that specified information is incomplete or unavailable, as the case may be; and
  - (b) an indication of the significance of the incomplete or unavailable information to the evaluation of the possible risks of the proposal in relation to the health and safety of people and the environment; and
  - (c) a summary of known existing scientific evidence relevant to such evaluation; and
  - (d) applying that summary — an evaluation of the possible risks based on theoretical approaches, and research methods, that are generally accepted in the scientific community.

*Note 1* Additional information, specified in writing by the Regulator, may also be required.

*Note 2* At the commencement of the Regulations, there is no fee payable for an application for a GMO licence

## **8 Time limit for deciding an application**

- (1) For subsection 43 (3) of the Act, the period within which the Regulator must issue, or refuse to issue, a licence is:
  - (a) in relation to an application to which Division 3 of Part 5 of the Act applies — 90 days after the day the application is received by the Regulator; or

**Regulation 8**

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- (b) in relation to an application to which Division 4 of Part 5 of the Act applies — 170 days after the day the application is received by the Regulator.
- (2) For the purpose of determining the end of a period mentioned in subregulation (1), the following days are not counted:
- (a) a Saturday, a Sunday or a public holiday in the Australian Capital Territory;
  - (b) a day on which the Regulator cannot proceed with the decision-making process, or a related function, because the Regulator is awaiting information that the applicant has been requested, in writing, to give;
  - (c) if, in relation to the application, the Regulator publishes notice of a public hearing under section 53 of the Act, a day in the period that:
    - (i) begins on the day of publication; and
    - (ii) ends on the day when the public hearing ends;
  - (d) a day on which the Regulator cannot proceed with the decision-making process, or a related function, because:
    - (i) the applicant has requested, under section 184 of the Act, that information given in relation to the application be declared confidential commercial information for the purposes of the Act; and
    - (ii) the Regulator is:
      - (A) considering the application; or
      - (B) waiting until any review rights under section 181 or 183 of the Act, in relation to the application, are exhausted;
  - (e) if, in relation to the application, the Regulator requests the Gene Technology Ethics Committee to provide advice on an ethical issue, a day in the period that:
    - (i) begins on the day the request is made; and
    - (ii) subject to subregulation (3) — ends on the day when the advice is given or, if the advice is not given within the period, if any, specified under subregulation (3), on the last day of that period.
- (3) The Regulator, when seeking advice under subsection 50 (3) or 52 (3) of the Act, or from the Gene Technology Ethics

Committee, may specify a reasonable period within which the advice must be received, and, if the advice is not received within that period, must proceed without regard to that advice.

## **9 Prescribed authorities**

For paragraphs 50 (3) (c) and 52 (3) (c) of the Act, the following Commonwealth authorities and agencies are prescribed:

- (a) Australia New Zealand Food Authority;
- (b) Australian Quarantine and Inspection Service;
- (c) National Health and Medical Research Council;
- (d) National Industrial Chemical Notification and Assessment Scheme, National Occupational Health and Safety Commission;
- (e) National Registration Authority for Agricultural and Veterinary Chemicals;
- (f) Therapeutic Goods Administration, Department of Health and Aged Care.

## **10 Risk assessment — matters to be taken into account**

- (1) For paragraphs 51 (1) (g) and 51 (2) (g) of the Act, other matters to be taken into account in relation to dealings proposed to be authorised by a licence include:
  - (a) any previous assessment, in Australia or overseas, in relation to allowing or approving dealings with the GMO; and
  - (b) the potential of the GMO concerned to:
    - (i) be harmful to other organisms; and
    - (ii) adversely affect any ecosystems; and
    - (iii) transfer genetic material to another organism; and
    - (iv) spread, or persist, in the environment; and
    - (v) have, in comparison to related organisms, selective advantage in the environment; and
    - (vi) be toxic, allergenic or pathogenic to other organisms.

## Regulation 11

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- (2) In taking into account a risk mentioned in subsection 51 (1) of the Act, or a potential capacity mentioned in subregulation (1), the Regulator must consider both the short term and the long term.

### 11 Prescribed conditions of licence

*Note* At the commencement of the Regulations, no conditions are prescribed under paragraph 61 (b) of the Act.

## Division 2 Notifiable low risk dealings

### 12 Notifiable low risk dealings

- (1) For subsection 74 (1) of the Act, a dealing with a GMO is a notifiable low risk dealing if:
- (a) it is a dealing of a kind mentioned in Part 1 of Schedule 3 (other than a dealing also mentioned in Part 2 of Schedule 3); and
  - (b) it does not involve an intentional release of the GMO into the environment.
- (2) For the avoidance of doubt, subregulation (1) does not apply to a dealing that does not comply with subregulation (1), whether or not that dealing is related to a dealing that does so comply.

*Note* A dealing affected by this regulation could be any of the forms of dealing mentioned in the definition of *deal with* in subsection 10 (1) of the Act.

### 13 Requirements in relation to notifiable low risk dealings

- (1) A person must not undertake a notifiable low risk dealing unless:
- (a) the proposed dealing has been assessed, by an Institutional Biosafety Committee, to be a dealing of a kind mentioned in Part 1 of Schedule 3; and

- (b) within 14 days after completion of the assessment — the Committee has notified the Regulator, by giving the Regulator, in relation to the proposed notifiable low risk dealing, the information specified in Part 3 of Schedule 3; and
  - (c) the person, and the project supervisor for the proposed dealing, have received written notice from the Committee that paragraph (b) has been complied with.
- (2) A notifiable low risk dealing, when undertaken, must comply with the following requirements:
- (a) the dealing must be conducted in a facility that:
    - (i) is certified by the Regulator to:
      - (A) at least physical containment level 2; or
      - (B) any other containment level that the Regulator considers suitable for conducting the dealing; and
    - (ii) is of appropriate design for the kind of dealing being undertaken;
  - (b) the conduct of the dealing must be properly supervised, and a record of details of the dealing kept;
  - (c) if the dealing involves human pathogens, it must be conducted only in accordance with the recommendations for vaccination given in Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology);
  - (d) to the extent that the dealing involves transporting a GMO, the transporting must be conducted in accordance with any relevant guidelines, as in force from time to time, issued by the Regulator.
- (3) For paragraph (1) (a), a proposed dealing is taken to be assessed if the assessment applies to:
- (a) in relation to the dealing — the particular GMO concerned, or a class of GMOs that includes that GMO; or
  - (b) in relation to the particular GMO, or class of GMOs — a class of dealings that includes that dealing.
- (4) From the commencement of these Regulations, until 2 years after the commencement, a person who complies with subregulation (2) may undertake a notifiable low risk dealing

**Regulation 14**

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although any, or all, of the provisions of subregulation (1) have not been complied with if there is in force a notice issued by, or on behalf of, the Genetic Manipulation Advisory Committee declaring that the dealing is a notifiable low risk dealing.

**Division 3 Certification and accreditation**

**14 Regulator to decide certification application within 90 days**

- (1) For section 84 of the Act, the period within which the Regulator must consider, and decide, an application for certification of a facility is:
  - (a) 90 days after the day the application is received by the Regulator; or
  - (b) if the Regulator has given the applicant a notice under subsection 85 (1) of the Act, 90 days plus the period beginning on the day the notice is given and ending when the required information is given to the Regulator.
- (2) For the purpose of determining the end of a period mentioned in subregulation (1), Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted.

**15 Application for certification — failure to provide section 85 information**

If an applicant for certification fails to provide information required under subsection 85 (1) of the Act within the period specified in a notice given under subsection 85 (2) of the Act, and gives no reasonable explanation for the failure, the Regulator may refuse to certify the facility that is the subject of the application.

*Note* A refusal to certify a facility is a reviewable decision (see Division 2 of Part 12 of the Act).

**16 Regulator to decide accreditation application within 90 days**

- (1) For subsection 92 (1) of the Act, the period within which the Regulator must consider, and decide, an application for accreditation of an organisation is:
  - (a) 90 days after the day the application is received by the Regulator; or
  - (b) if the Regulator has given the applicant a notice under subsection 93 (1) of the Act, 90 days plus the period beginning on the day the notice is given and ending when the required information is given to the Regulator.
- (2) For the purpose of determining the end of a period mentioned in subregulation (1), Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted.

**17 Application for accreditation — failure to provide section 93 information**

If an applicant for accreditation fails to provide information required under subsection 93 (1) of the Act within the period specified in a notice given under subsection 93 (2) of the Act, and gives no reasonable explanation for the failure, the Regulator may refuse to accredit the organisation that is the subject of the application.

*Note* A refusal to accredit an organisation is a reviewable decision (see Division 2 of Part 12 of the Act).

## **Part 4 Gene Technology Technical Advisory Committee**

### **Division 1 Conditions of appointment**

#### **18 GTTAC members and advisers — term of appointment**

- (1) The term of appointment of a member of the Gene Technology Technical Advisory Committee, or an expert adviser, is 3 years, or a lesser period specified in the instrument of appointment of the member or adviser.
- (2) A member or adviser may be reappointed for a further term or terms.

#### **19 GTTAC members and advisers — resignation**

A member of the Gene Technology Technical Advisory Committee, or an expert adviser, may resign by giving the Minister written notice of resignation.

#### **20 GTTAC members — disclosure of interests**

- (1) Before the Minister appoints a person as a member of the Gene Technology Technical Advisory Committee, the Minister must obtain from the person a declaration setting out all direct or indirect interests, pecuniary or otherwise, that the person is aware of having in a matter of a kind likely to be considered at a meeting of the Committee.
- (2) A member of the Gene Technology Technical Advisory Committee who is aware of having a direct or indirect interest, pecuniary or otherwise, in a matter being considered, or about to be considered, at a meeting of the Committee must, without delay, disclose the nature of the interest at, or before, the meeting of the Committee.



**Regulation 21**

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- (3) Disclosure must include interests that could be perceived to represent a possible conflict of interest in relation to:
  - (a) for subregulation (1) — a matter likely to be considered at a meeting of the Committee; or
  - (b) for subregulation (2) — the matter being considered or about to be considered.
- (4) A disclosure under this regulation must be recorded in the minutes of the meeting and the member must not:
  - (a) be present during any deliberation of the Committee about the matter, except to give information requested by the Committee; or
  - (b) take part in any decision of the Committee about that matter.

**21 GTTAC members and advisers — termination of appointment**

- (1) The Minister may terminate the appointment of a member of the Gene Technology Technical Advisory Committee, or an expert adviser, for misbehaviour (including failure to disclose an interest) or physical or mental incapacity:
  - (a) in the case of the chairperson of the Committee — with the agreement of a majority of jurisdictions; or
  - (b) in any other case — on the initiative of the Minister.
- (2) The Minister must terminate a member's appointment if the member:
  - (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 fulfil his or her obligations, as a member, in enabling the Committee to comply with section 101 of the Act; or
  - (c) fails to attend for 3 consecutive attendance days of the Committee, except with leave of absence granted under regulation 22.

*Note* Under section 27A of the *Administrative Appeals Tribunal Act 1975*, a decision-maker must give to persons whose interests are affected by the

**Regulation 22**

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making of the decision, notice of the decision and of their right to have the decision reviewed. In notifying such a person, the decision-maker must have regard to the Code of Practice determined under section 27B of that Act (see *Gazette* No. S 432, 7 December 1994), which is accessible on the Internet at:

<http://scaleplus.law.gov.au/html/instruments/0/14/0/IN000020.htm>.

**22 GTTAC members — leave of absence**

- (1) The Minister may grant the Chairperson of the Gene Technology Technical Advisory Committee leave of absence.
- (2) The Chairperson may grant a member of the Gene Technology Technical Advisory Committee leave of absence.

**23 Expert advisers — disclosure of interests**

- (1) Before the Minister appoints a person as an expert adviser to the Gene Technology Technical Advisory Committee, the Minister must obtain from the person a declaration setting out all direct or indirect interests, pecuniary or otherwise, that the person is aware of having in a matter of a kind likely to be considered at a meeting of the Committee.
- (2) An expert adviser who is aware of having a direct or indirect interest, pecuniary or otherwise, in a matter being considered, or about to be considered, at a meeting of the Committee for which he or she is providing advice must, without delay, disclose the nature of the interest at, or before, the meeting of the Committee.
- (3) Disclosure must include interests that could be perceived to represent a possible conflict of interest in relation to:
  - (a) for subregulation (1) — a matter likely to be considered at a meeting of the Committee; or
  - (b) for subregulation (2) — the matter being considered or about to be considered.
- (4) A disclosure under this regulation must be recorded in the minutes of the meeting.

## **Division 2                      Committee procedures**

### **24                      Committee procedures generally**

In performing its functions, the Gene Technology Technical Advisory Committee:

- (a) must act according to these Regulations; and
- (b) must act with as little formality and as quickly as the requirements of these Regulations, and a proper consideration of the issues before the Committee, allow; and
- (c) may obtain information about an issue in any way it considers appropriate, subject to any direction in a request from the Regulator or Ministerial Council about the extent to which, or manner in which, information is to be obtained.

### **25                      Committee meetings**

- (1) The Chairperson of the Gene Technology Technical Advisory Committee may, by written notice to the Committee, direct the Committee to hold a meeting:
  - (a) at the time and place stated in the notice; and
  - (b) to deal with specified matters in the manner stated in the notice.
- (2) In each year, the Committee may have as many meetings (other than meetings by videoconference or teleconference) as:
  - (a) before the beginning of the year — the Regulator and the Chairperson have agreed may be held; and
  - (b) the Regulator and the Chairperson agree should be additionally held.
- (3) If the Chairperson of the Committee considers it appropriate and efficient in the circumstances, the Committee may be directed:
  - (a) to meet, and resolve decisions, by videoconference or teleconference; and
  - (b) to meet out of session.

**Regulation 26**

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- (4) For this regulation:  
*out of session*, in relation to a meeting, means a meeting in which the members take part by correspondence, electronic mail, telephone or in any other way that does not involve formal simultaneous meeting and voting.
- (5) Subject to these Regulations, the procedure of a meeting is as decided by the Committee.

**26 Presiding member**

- (1) At a meeting of the Gene Technology Technical Advisory Committee, the Chairperson of the Committee must:
- (a) preside; or
  - (b) nominate, in writing, a member of the Committee (other than a member to whom paragraph 100 (7A) (a) or (b) of the Act applies) to preside.
- (2) If the Chairperson is temporarily absent from a meeting, the members present must choose a member to preside in the Chairperson's absence.

**27 Quorum**

At a meeting of the Gene Technology Technical Advisory Committee, a quorum exists if half of the members appointed under subsection 100 (2) of the Act are present.

**28 Voting**

- (1) A decision of the Gene Technology Technical Advisory Committee is made by a majority of the members present, and voting for the decision, at a Committee meeting.
- (2) The member presiding at a Committee meeting has a deliberative vote and also has a casting vote in the event of an equality of votes by members present.

**29 Records and Reports**

- (1) The Gene Technology Technical Advisory Committee must keep a record of its proceedings, and must give to the Regulator a copy of each resolution passed by the Committee.
- (2) Copies of resolutions are to be maintained by the Regulator in a form accessible to the public, except to the extent that information in a resolution is considered by the Regulator to be confidential commercial information.
- (3) The Committee must prepare any other report about its activities that is requested by the Minister or the Regulator.

**Division 3 Subcommittees****30 Operation of subcommittees**

- (1) Regulations 24, 25, 26 and 28 apply to a subcommittee established under subsection 105 (1) of the Act as if a reference in those regulations to the Gene Technology Technical Advisory Committee were a reference to the subcommittee.
- (2) At a meeting of a subcommittee, a quorum exists if half of the members of the subcommittee are present.
- (3) A subcommittee must keep a record of its proceedings, and must give to the Gene Technology Technical Advisory Committee a copy of each resolution passed by the subcommittee.

**Regulation 31**

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## **Part 5                                      Gene Technology Community Consultative Committee**

### **31                      GTCCC — conditions of appointment**

Division 1 of Part 4 applies to the conditions of appointment of a member of the Gene Technology Community Consultative Committee as if:

- (a) a reference to the Gene Technology Technical Advisory Committee were a reference to the Gene Technology Community Consultative Committee; and
- (b) a reference to a member of the Gene Technology Technical Advisory Committee were a reference to a member of the Gene Technology Community Consultative Committee; and
- (c) the reference, in paragraph 21 (2) (b), to section 101 of the Act were a reference to section 107 of the Act.

### **32                      GTCCC — Consultative Committee procedures**

Division 2 of Part 4 applies to the procedures of the Gene Technology Community Consultative Committee as if:

- (a) a reference to the Gene Technology Technical Advisory Committee were a reference to the Gene Technology Community Consultative Committee; and
- (b) a reference to a member or Chairperson of the Gene Technology Technical Advisory Committee were a reference to a member or Chairperson of the Gene Technology Community Consultative Committee; and
- (c) the reference, in paragraph 26 (1) (b), to paragraph 100 (7A) (a) or (b) of the Act were a reference to paragraph 108 (4) (a) or (b) of the Act; and
- (d) the reference, in regulation 27, to subsection 100 (2) of the Act were a reference to subsection 108 (1) of the Act.

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**Regulation 33**

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**33 GTCCC — operation of subcommittees**

- (1) Regulations 24, 25, 26 and 28 apply to a subcommittee established under subsection 110A(1) of the Act as if a reference in those regulations to the Gene Technology Technical Advisory Committee were a reference to the subcommittee.
- (2) At a meeting of a subcommittee, a quorum exists if half of the members of the subcommittee are present.
- (3) A subcommittee must keep a record of its proceedings, and must give to the Gene Technology Community Consultative Committee a copy of each resolution passed by the subcommittee.

## Part 6 Gene Technology Ethics Committee

### 34 GTEC — Conditions of appointment

- (1) Division 1 of Part 4 applies to the conditions of appointment of a member of the Gene Technology Ethics Committee, or an expert adviser, as if:
- (a) a reference to the Gene Technology Technical Advisory Committee were a reference to the Gene Technology Ethics Committee; and
  - (b) a reference to a member of the Gene Technology Technical Advisory Committee were a reference to a member of the Gene Technology Ethics Committee; and
  - (c) the reference, in paragraph 21 (2) (b), to section 101 of the Act were a reference to section 112 of the Act.

### 35 GTEC — Committee procedures

Division 2 of Part 4 applies to the procedures of the Gene Technology Ethics Committee as if:

- (a) a reference to the Gene Technology Technical Advisory Committee were a reference to the Gene Technology Ethics Committee; and
- (b) a reference to a member or Chairperson of the Gene Technology Technical Advisory Committee were a reference to a member or Chairperson of the Gene Technology Ethics Committee; and
- (c) the reference, in paragraph 26 (1) (b), to paragraph 100 (7A) (a) or (b) of the Act were a reference to paragraph 111 (6) (a) or (b) of the Act; and
- (d) the reference, in regulation 27, to subsection 100 (2) of the Act were a reference to subsection 111 (2) of the Act.



**Regulation 36**

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**36 GTEC — operation of subcommittees**

- (1) Regulations 24, 25, 26 and 28 apply to a subcommittee established under subsection 116 (1) of the Act as if a reference in those regulations to the Gene Technology Technical Advisory Committee were a reference to the subcommittee.
- (2) At a meeting of a subcommittee, a quorum exists if half of the members of the subcommittee are present.
- (3) A subcommittee must keep a record of its proceedings, and must give to the Gene Technology Ethics Committee a copy of each resolution passed by the subcommittee.

**Regulation 37**

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**Part 7                            Miscellaneous**

**37            Reviewable State decisions**

*Note* At the commencement of these Regulations, no decisions of the Regulator are reviewable State decisions under section 19 of the Act.

**38            Review of decisions**

Subject to the *Administrative Appeals Tribunal Act 1975*, a person whose interests are affected by a decision of the Minister under regulation 21, or that regulation as applied to Part 5 or Part 6 of these Regulations, may apply to the Administrative Appeals Tribunal for review of the decision.

**39            Record of GMO and GM Product Dealings**

- (1) For subsection 138 (4) of the Act, the following particulars are prescribed in relation to a notifiable low risk dealing that is notified to the Regulator:
  - (a) the name of the organisation proposing to undertake the notified dealing;
  - (b) in terms of Part 1 of Schedule 3 — the kind of notifiable low risk dealing proposed;
  - (c) the identifying name given to the proposed undertaking by the organisation;
  - (d) the date of the notification.
- (2) For subsection 138 (5) of the Act, the following particulars are prescribed in relation to a GM product mentioned in a designated notification:
  - (a) the name of the organisation producing the GM product;
  - (b) a description of the GM product, with reference to:
    - (i) the *applicable Act* (that is, whichever of the following Acts is applicable):
      - (A) *Agricultural and Veterinary Chemicals (Administration) Act 1992*;

**Regulation 40**

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- (B) *Australia New Zealand Food Authority Act 1991*;
  - (C) *Industrial Chemicals (Notification and Assessment) Act 1989*;
  - (D) *Therapeutic Goods Act 1989*; and
- (ii) its common name as a product, or type or class of product (for example, bread or insulin);
- (c) information about the GM product, including:
    - (i) the common name and the scientific name of the parent organism involved; and
    - (ii) details of the introduced trait in the GM product; and
    - (iii) the identity of the introduced gene responsible for conferring the introduced trait;
  - (d) the date on which a decision under the applicable Act, that enables supply of the GM product in Australia, takes effect;
  - (e) details of any conditions attaching to that permission.

**40 Inspector identity card**

For paragraph 151 (2) (a) of the Act, an inspector's identity card must:

- (a) display a recent photograph of the inspector's face; and
- (b) state the date of issue; and
- (c) state the period of its validity.

Regulation 41

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## Part 8 Transitional

### 41 Existing facilities — certification

- (1) If, at the commencement of Part 7 of the Act, there is in force for an existing facility a notice from the Genetic Manipulation Advisory Committee that the facility provides a specified physical containment level, the facility is taken to be certified to that physical containment level under section 84 of the Act.
- (2) Subregulation (1) applies:
  - (a) subject to paragraphs 86 (b) and (c) of the Act and sections 87 and 88 of the Act; and
  - (b) for a facility in relation to which the notice specifies that it is a physical containment level 2 facility (other than a PC2 Large Scale facility) — until the end of 2 years after the commencement of Part 7 of the Act, provided the facility maintains compliance with the Regulator's guidelines about the requirements for certification at that level; and
  - (c) for a facility in relation to which the notice specifies that it is a physical containment level 3 or level 4 facility, a PC2 Large Scale facility or a facility providing appropriate physical containment for a specified purpose — until the end of 1 year after the commencement of Part 7 of the Act, provided the facility maintains compliance with the Regulator's guidelines about the requirements for certification at its specified containment level.
- (3) For subregulation (2):

**PC2 Large Scale facility** means a physical containment level 2 facility so described by the notice given in relation to the facility by the Genetic Manipulation Advisory Committee.

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**Regulation 42**

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**42 Existing organisations — accreditation**

- (1) If, at the commencement of Part 7 of the Act, there is in force for an existing organisation a notice from the Genetic Manipulation Advisory Committee that the organisation is an accredited organisation, the organisation is taken to be an accredited organisation under section 92 of the Act.
- (2) Subregulation (1) applies:
  - (a) subject to paragraphs 94 (b) and (c) of the Act and sections 95 and 96 of the Act; and
  - (b) until the end of 2 years after the commencement of Part 7 of the Act, provided the organisation maintains compliance with the Regulator's guidelines, if any, under section 98 of the Act.

# Schedule 1 Organisms that are not genetically modified organisms

(regulation 5)

## Part 1 Organisms

Item	Description of organism
1	A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).
2	A recombinant organism formed through integration into chromosomal or extrachromosomal DNA sequences of a genetic element that: (a) occurs naturally in the species concerned; and (b) moves sporadically between genome sites.
3	An organism that: (a) results from the fusion of 2 animal cells; and (b) is unable to form a viable whole animal.  <i>Example</i> Organisms of the kind described include hybridomas created to produce monoclonal antibodies.
4	An organism that results from protoplast fusion involving only non-pathogenic bacteria or non-pathogenic yeast.
5	A plant formed by: (a) embryo rescue; or (b) <i>in vitro</i> fertilisation; or (c) zygote implantation; or (d) protoplast fusion.
6	An organism that results from an exchange of DNA if: (a) the donor species is also the host species; and (b) the vector DNA does not contain any heterologous DNA.

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<b>Item</b>	<b>Description of organism</b>
7	An organism that results from an exchange of DNA between the donor species and the host species if: <ul style="list-style-type: none"><li>(a) such exchange can occur by naturally occurring processes; and</li><li>(b) the donor species and the host species are both mentioned in the same group in Part 2 of this Schedule; and</li><li>(c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange.</li></ul>

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## **Part 2      Species known to exchange DNA by a known physiological process**

### **Group 1**

Alcaligenes  
Campylobacter coli  
Campylobacter fetus  
Campylobacter jejuni  
Citrobacter (including levinea)  
Enterobacter  
Erwinia  
Escherichia  
Klebsiella  
Pseudomonas aeruginosa  
Pseudomonas fluorescens  
Pseudomonas mendocina  
Pseudomonas putida  
Rhizobium  
Salmonella (including arizona)  
Serratia marcescens  
Shigella  
Yersinia enterocolitica

## Group 2

*Bacillus amyloliquefaciens*  
*Bacillus atterimus*  
*Bacillus globigii*  
*Bacillus licheniformis*  
*Bacillus nato*  
*Bacillus niger*  
*Bacillus pumilus*  
*Bacillus subtilis*

## Group 3

*Streptomyces aureofaciens*  
*Streptomyces coelicor*  
*Streptomyces rimosus*

## Group 4

*Streptomyces cyaneus*  
*Streptomyces griseus*  
*Streptomyces venezuela*

## Group 5

*Streptococcus mutans* DNA and *Streptococcus lactis* DNA — in a one-way transfer into *Streptococcus sanguis*

## Group 6

*Streptococcus faecalis*  
*Streptococcus mutans*  
*Streptococcus pneumoniae*  
*Streptococcus pyogenes*  
*Streptococcus sanguis*

## Group 7

*Bacillus cereus*  
*Bacillus thuringiensis*



## Schedule 2      Dealings exempt from licensing

(regulation 6)

*Note* Subregulation 6 (1) sets out other requirements for exempt dealings.

### Part 1      Exempt dealings

Item	Description of dealing
1	Any dealing with gene-knockout mice (that is, mice whose genetic modification involves deletion or inactivation of a specific gene), if no advantage is conferred on the adult animal: <ul style="list-style-type: none"><li>(a) by the deletion or inactivation of the gene concerned; or</li><li>(b) for mice that also carry a selectable marker gene — by the selectable marker gene.</li></ul>
2	Any dealing with a whole animal, if: <ul style="list-style-type: none"><li>(a) naked recombinant nucleic acid has been introduced into its somatic cells; and</li><li>(b) the introduced nucleic acid is incapable of giving rise to infectious agents.</li></ul>
3	Any dealing with an animal into which genetically modified somatic cells have been introduced, unless the cells: <ul style="list-style-type: none"><li>(a) are capable of giving rise to recombinant infectious agents; or</li><li>(b) contain viral sequences that could recombine with, or be complemented by, genomes of introduced superinfecting viruses.</li></ul>
4	Any dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture, if: <ul style="list-style-type: none"><li>(a) the donor DNA:<ul style="list-style-type: none"><li>(i) is not derived from micro-organisms capable of causing disease in human beings, other animals, plants or fungi, or is fully characterised and will not increase the virulence or host range of the host or vector; and</li><li>(ii) is not an oncogene; and</li></ul></li></ul>

Item	Description of dealing
	<ul style="list-style-type: none"> <li>(iii) does not code for a toxin for vertebrates with an LD50 of less than 100 µg/kg; and</li> <li>(iv) does not code for a toxin for vertebrates with an LD50 of 100 µg/kg or more, if the intention is to express the toxin at high levels; and</li> <li>(v) is not uncharacterised DNA from a micro-organism that produces toxins with an LD50 of 100 µg/kg or less; or</li> </ul>
	(b) the donor DNA includes a viral sequence or viral sequences, but: <ul style="list-style-type: none"> <li>(i) is missing at least 1 gene essential for viral multiplication that is not available in the cell into which the DNA is introduced and that will not become available through subsequent breeding; and</li> <li>(ii) is incapable of complementing a defect in the host/vector system.</li> </ul>
5	Any dealing involving shot-gun cloning of mammalian DNA in a host/vector system mentioned in Part 2 of this Schedule.

## Part 2 Host/vector systems for exempt dealings

Item	Class	Host	Vector
1	Bacteria	<i>Escherichia coli</i> K12 or <i>E. coli</i> B – any derivative that does not contain: <ul style="list-style-type: none"> <li>(a) conjugative or generalised transducing phages; or</li> <li>(b) genes able to complement the conjugation defect in a non-conjugative plasmid</li> </ul>	1. Non-conjugative plasmids 2. Bacteriophage <ul style="list-style-type: none"> <li>(a) lambda</li> <li>(b) lambdoid</li> <li>(c) Fd or F1 (eg M13)</li> </ul>
2		<i>Bacillus subtilis</i> or <i>B. licheniformis</i> – an asporogenic strain with a reversion frequency of less than 10 <sup>-7</sup>	Plasmids and phages whose host range does not include <i>B. cereus</i> , <i>B. anthracis</i> or any other pathogenic strain of bacillus
3		<i>Pseudomonas putida</i> – strain KT 2440	Certified plasmids: pKT 262, pKT 263, pKT 264

Item	Class	Host	Vector
4		<i>Streptomyces</i> – specified species: (a) <i>S. coelicolor</i> (b) <i>S. lividans</i> (c) <i>S. parvulus</i> (d) <i>S. griseus</i>	1. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 2. Actinophage phi C31 and derivatives
	Fungi	<i>Neurospora crassa</i> – laboratory strains	All vectors
		<i>Pichia pastoris</i>	All vectors
		<i>Saccharomyces cerevisiae</i>	All vectors
		<i>Schizosaccharomyces pombe</i>	All vectors
		<i>Kluyveromyces lactis</i>	All vectors
		<i>Trichoderma reesei</i>	All vectors
	Slime moulds	<i>Dictyostelium</i> species	<i>Dictyostelium</i> shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2
	Tissue culture	Mammalian (including human) cells and cells of aquatic organisms	Non-viral vectors or defective viral vectors (including retrovirus or retroviral-helper combinations that cannot infect human cells)
		Avian cells	Avipoxvirus vectors (attenuated vaccine strains)
		Plant cell cultures	Non-tumorigenic disarmed Ti plasmid vectors in <i>Agrobacterium tumefaciens</i> and non-pathogenic viral vectors
		Insect cell cultures, such as <i>Spodoptera frugiperda</i> , if the recombinants are also inclusion-negative (eg polyhedrin minus)	Baculovirus ( <i>Autographa californica</i> nuclear polyhedrosis virus), polyhedrin minus

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Item	Class	Host	Vector
5		Any host mentioned, or of a kind mentioned, in any of items 1 to 4	Any non-biological vector (for example, electrocorporation or particle bombardment)

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### Part 3 Definitions

In this Schedule:

**advantage**, in relation to an adult animal that is genetically modified, means a superior ability in its modified form, relative to the unmodified parental organism, to survive, reproduce or otherwise contribute to the gene pool.

**characterised**, in relation to DNA, means that the DNA has been sequenced and that there is an understanding of potential gene products of the DNA.

**code for**, in relation to a toxin, means to specify the amino acid sequence of the toxin.

**inclusion-negative**, in relation to a recombinant of insect cell cultures, means the vector baculovirus used is in a mutant form that is unable to make polyhedrin (a material surrounding a virus and protecting it from adverse environmental effects such as UV radiation).

**recombinant**, in relation to matter that is a sequence or an organism, means matter of that kind containing recombinant DNA (that is, DNA formed by joining, *in vitro*, segments of DNA from different organisms).

**shot-gun cloning**, in relation to mammalian DNA, means the production of a large random collection of cloned fragments of the DNA from which genes of interest can later be selected.

**toxin producing organism** means an organism producing toxin with an LD50 of less than 100 µg/kg.

## **Schedule 3      Notifiable low risk dealings in relation to a GMO**

(regulations 12 and 13)

### **Part 1      Dealings that are notifiable low risk dealings**

*Note* Because of subregulation 13 (1) a dealing mentioned in this Part is not a notifiable low risk dealing if it is also a dealing of a kind mentioned in Part 2 of this Schedule.

#### **1.1      Kinds of dealings**

The following kinds of dealings are notifiable low risk dealings:

- (a) any dealing involving whole animals (including non-vertebrates) that:
  - (i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and
  - (ii) does not involve gene-knockout mice;
- (b) any dealing involving a genetically modified flowering plant, if:
  - (i) the dealing does not involve the plant being grown to flowering stage; or
  - (ii) for a dealing that does involve the plant being grown to flowering stage:
    - (A) the plant is male sterile and is unable to set seed; or
    - (B) if the plant is male sterile and can set seed — all vents and drains in the facility are screened with mesh or filters that block the escape of viable pollen and seed; or

- (C) before flowering, all inflorescences are wholly enclosed in bags designed to prevent escape of viable pollen and seed; or
  - (D) if the plant can be wind-pollinated — all vents and drains in the facility are screened with mesh or filters that block the escape of viable pollen and seed; or
  - (E) if the plant can be vector-pollinated only — all vents and drains in the facility are screened with mesh or filters that block the escape of viable seed and exclude pollen vectors from the facility;
- (c) any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if:
- (i) the host is incapable of causing disease in human beings, animals, plants or fungi; and
  - (ii) the vector is incapable of causing disease in human beings, animals, plants or fungi;
- (d) any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if, although the host or vector is capable of causing disease in human beings, animals, plants or fungi, the donor DNA is fully characterised and will not increase the virulence of the host or vector;
- (e) any dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the gene inserted:
- (i) is a pathogenic determinant; or
  - (ii) is uncharacterised DNA from a micro-organism that is capable of causing disease in human beings, animals, plants or fungi; or
  - (iii) is an oncogene.

## 1.2 Definitions

In this Part:

*characterised*, in relation to DNA, means that the DNA has been sequenced and that there is an understanding of potential gene products of the DNA.

*gene-knockout mice*, has the same meaning as in item 1 in Part 1 of Schedule 2.

## Part 2 Dealings (higher risk) that are not notifiable low risk dealings

*Note 1* The following list qualifies the list in Part 1, and is not an exhaustive list of dealings that are not notifiable low risk dealings.

*Note 2* A dealing that is not a notifiable low risk dealing, or an exempt dealing, can be undertaken only by a person who is licensed, under the Act, for the dealing (see Act, section 32).

### 2.1 Kinds of dealings

A dealing of any of the following kinds, or involving a dealing of the following kinds, is not a notifiable low risk dealing:

- (a) a dealing involving cloning of DNA encoding a toxin for vertebrates having an LD50 of less than 100 µg/kg;
- (b) a dealing involving high level expression of toxin genes, even if the LD50 is greater than 100 µg/kg;
- (c) a dealing involving cloning of uncharacterised DNA from toxin-producing micro-organisms;
- (d) a dealing involving a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2), containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells;
- (e) a dealing involving, as host or vector, a micro-organism that is capable of causing disease in humans, animals plants or fungi, unless:
  - (i) the host/vector system is a system mentioned in Part 2 of Schedule 2; or
  - (ii) the dealing involves only the cloning of DNA that is fully characterised and is known not to increase the virulence of the host and vector;

- (f) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes that determine pathogenicity;
- (g) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes whose expressed products have a heightened risk of inducing an autoimmune response;
- (h) a dealing involving cloning or transfer of fragments of a viral or viroid genome that are capable, in the host/vector system to be used, of giving rise to infectious agents that are capable of infecting cells of human, animal, plant or fungal origin;
- (i) a dealing involving recombination between whole viral genomes, viroids or complementing fragments of such genomes (if one or more fragments contain virulence or pathogenic determinants);
- (j) a dealing involving use of a viral vector to produce a transgenic animal, plant or fungus that secretes or produces infectious recombinant viral agents;
- (k) a dealing involving the production of more than 10 litres of GMO culture;
- (l) a dealing that is inconsistent with a policy principle issued by the Ministerial Council.

### **Part 3 Prescribed information — notification of proposed notifiable low risk dealing**

#### **3.1 Information about proponent and proposed dealing**

For a notification made under paragraph 15 (1) (b) of these Regulations, the following information must be included:

##### **3.1.1 General information**

- (a) name, address, telephone number and other contact details, of the proponent organisation;
- (b) name, position within the organisation and contact details, of the proponent's project supervisor for the proposed dealing, or dealings, with the GMO or GMOs involved;



- 
- (c) title of the project involving the proposed dealing or dealings;
  - (d) with reference to the kinds of dealings set out in Part 1 of this Schedule — the kind of dealing or dealings proposed;
  - (e) description of each GMO involved;
    - (i) the common name of the parent organism; and
    - (ii) the scientific name of the parent organism; and
    - (iii) the modified trait; and
    - (iv) the identity of the gene responsible for the modified trait;
  - (f) description of the proposed dealing or dealings;
  - (g) description of the purposes and aims of the proposed dealing or dealings;
  - (h) address of the premises where the dealing is, or dealings are, proposed to be undertaken;
  - (i) proposed date of commencement, and proposed date of completion, of the dealing or dealings.

### 3.1.2 *Genetics of GMO*

- (a) details of the biological system intended to be used, including:
  - (i) the biological source of the donor DNA; and
  - (ii) the intended host organism, or tissue; and
  - (iii) the vector or vectors, or the method, intended to be used for the transfer of DNA; and
  - (iv) whether the intended host/vector system is a system mentioned in Part 2 of Schedule 2.

### 3.1.3 *Risk assessment information*

- (a) details of all risks that could arise from the genetic modification, including occupational health and safety risks for persons involved;
- (b) details of all risks that could arise from an unintentional release of the GMO or GMOs into the environment, including:
  - (i) risks to the health and safety of people; and
  - (ii) risks to the environment.

### 3.1.4 *Risk management information*

- (a) details of the facility in which the proposed dealing or dealings are to be undertaken, and of its physical containment level (as certified under Division 2 of Part 7 of the Act);
- (b) in relation to certification of the facility:
  - (i) the date of certification; and
  - (ii) the certification number allocated to the facility by the Regulator; and
  - (iii) the date of the most recent inspection of the facility by the Regulator or the facility's Institutional Biosafety Committee;
- (c) if the GMO is, or GMOs are, intended to be transported or moved outside the facility, details of the arrangements for that transport or movement;
- (d) details of any arrangements for disposal of the GMO or GMOs;
- (e) details of action proposed to be taken in the case of an unintentional release of the GMO, or GMOs, from containment;
- (f) details of other actions and precautions proposed to be taken by the applicant to minimise any risks posed by the proposed dealing or dealings;
- (g) details of the qualifications and experience of the project supervisor for the proponent organisation.

### 3.2 **Additional information if GMO is a whole plant, or is to be used in conjunction with a whole plant**

For a notification about a proposed notifiable low risk dealing that will involve a GMO that is a whole plant, or the use of a GMO in conjunction with a whole plant, the following additional information must be included:

- (a) a statement on whether the parent organism is a weed or closely related to plants that are weeds and, if so, identification of the weeds that are closely related;
- (b) details of the stage of development that the plant, or plants, used in the dealing will be allowed to reach;

- (c) details of the method that will be used to dispose of the plant, or plants, used in the dealing;
- (d) a statement on whether soil, or soil substitute, will be used as the growing medium for the plant, or plants, used in the dealing, and, if so, details of how that medium will be subsequently sterilised or disposed of.

### 3.3 Supporting information from IBC for a proponent

The information required for a notification about a proposed notifiable low risk dealing includes the following information to be given in relation to the Institutional Biosafety Committee (*IBC*) concerned:

- (a) confirmation that the information given to the Regulator in relation to the proponent has been checked by the IBC and found to be complete;
- (b) confirmation that the IBC considers that personnel intended to be involved in dealing with the GMO or GMOs have adequate training and experience for the task;
- (c) a statement that the IBC has evaluated the proposed project, and that includes the following details:
  - (i) the date of the evaluation;
  - (ii) the full name of the IBC;
  - (iii) the name and contact details of the chairperson and of the secretary of the IBC;
- (d) a copy of the evaluation report, prepared in accordance with any guidelines issued by the Regulator;
- (e) a statement that the IBC is established in accordance with the Regulator's guidelines under section 98 of the Act.

*Note* The IBC giving the information could be an IBC established by the proponent, or by another accredited organisation.

## **Schedule 4 Prescribed information — application for a licence**

(regulation 7)

### **Part 1 Dealings not involving an intentional release of a GMO into the environment (Division 3 of Part 5 of the Act)**

#### **1.1 Information to be given by all applicants**

For an application to which Division 3 of Part 5 of the Act applies (a *Division 3 application*), the following information is required:

##### **1.1.1 General information**

- (a) name, address, telephone number and other contact details, of applicant;
- (b) name, position within the organisation and contact details, of applicant's project supervisor in relation to the proposed dealing, or dealings, with the GMO or GMOs involved;
- (c) title of the project involving the proposed dealing or dealings;
- (d) description of the GMO or GMOs involved, including:
  - (i) the common name of the parent organism; and
  - (ii) the scientific name of the parent organism; and
  - (iii) the modified trait; and
  - (iv) the identity of the gene responsible for the modified trait;
- (e) description of the proposed dealing or dealings;
- (f) description of the purposes and aims of the dealing or dealings;
- (g) address of the premises where the dealing is, or dealings are, proposed to be undertaken;

- (h) proposed date of commencement, and proposed date of completion, of the dealing or dealings.

*1.1.2 Genetics of the GMO*

- (a) details of the biological system intended to be used, including:
- (i) the biological source of the donor DNA; and
  - (ii) the intended host organism, or tissue; and
  - (iii) the vector or vectors, or the method, intended to be used for the transfer of DNA; and
  - (iv) whether the intended host/vector system is a system mentioned in Part 2 of Schedule 2.

*1.1.3 Risk assessment information*

- (a) details of all risks that could arise from the genetic modification, including occupational health and safety risks for persons involved;
- (b) details of all risks that could arise from an unintentional release of the GMO or GMOs into the environment, including:
- (i) risks to the health and safety of people; and
  - (ii) risks to the environment;
- (c) details of all previous applications (whether successful or unsuccessful) made under the Act, or to the Genetic Manipulation Advisory Committee, in relation to a proposed dealing with the GMO or GMOs, setting out in relation to each:
- (i) any reference number given to the application by the Regulator or the Genetic Manipulation Advisory Committee; and
  - (ii) the date of the application; and
  - (iii) the name of the applicant's project supervisor, or intended supervisor.

**1.1.4 Risk management information**

- (a) details of the facility in which the dealing or dealings are to be undertaken, and of its physical containment level (as certified under Division 2 of Part 7 of the Act);
- (b) in relation to certification of the facility:
  - (i) the date of certification; and
  - (ii) the certification number allocated to the facility by the Regulator; and
  - (iii) the date of the most recent inspection of the facility by the Regulator or the facility's Institutional Biosafety Committee;
- (c) if the GMO is, or GMOs are, intended to be transported or moved outside the facility, details of the arrangements for that transport or movement;
- (d) details of any arrangements for disposal of the GMO or GMOs;
- (e) details of action proposed to be taken in the case of an unintentional release of the GMO, or GMOs, from containment;
- (f) details of other actions and precautions proposed to be taken by the applicant to minimise any risks posed by the proposed dealing or dealings;
- (g) details of the qualifications and experience of the project supervisor for the proponent organisation.

**1.1.5 Suitability of the applicant**

(if the information is not already provided to the Regulator for any other purpose)

- (a) a copy of the applicant's statutory annual report, or other information about the financial viability of the applicant;
- (b) for section 58 of the Act, details of any relevant convictions (within the meaning of that section) of the applicant or the project supervisor;
- (c) for section 58 of the Act, details of any failure to comply with:
  - (i) a provision of the Act or the Regulations; or

- (ii) a condition of a licence or permit (within the meaning of paragraph 58 (1) (b) or 58 (2) (c) of the Act), particularly if resulting in a revocation or suspension;
- (d) details of any failure to comply with an advice to proceed issued by the Genetic Manipulation Advisory Committee;
- (e) details of applicant's capacity to manage any risks posed by the proposed dealing or dealings.

## 1.2 **Additional information if volume of GMO culture exceeds 10 litres**

If a GMO will be produced as a culture of cells exceeding 10 litres in volume, the following additional information is required for a Division 3 application:

- (a) details of the size of the proposed project, in terms of the volume of GMO culture to be produced and the area of the facility affected;
- (b) details of the main product, or products, of the intended dealing, or dealings, by-products (if any, including effluents) and the concentrations of those products and by-products at different stages of the production process;
- (c) details of precautions proposed to be taken to prevent any unintended dispersal of the GMO;
- (d) details of how genetic stability of the GMO will be checked, and at what frequency;
- (e) details of the plan, procedures and data collection program to be used to ensure the purity of the main product or products;
- (f) details of the facility to be used for the proposed project, including:
  - (i) the physical arrangements for each working unit involved; and
  - (ii) the operational procedures of each unit; and
  - (iii) how the intended level of physical confinement of GMOs is to be achieved;

- (g) details of arrangements for personnel management, including:
  - (i) supervision; and
  - (ii) training; and
  - (iii) health surveillance; and
  - (iv) emergency care;
- (h) details of the justification for the containment level proposed;
- (i) details of the project designs dealing with the risks mentioned in paragraphs (a) and (b) of item 1.1.3;
- (j) a statement on whether the site, within the host genome, of integration of the resultant transgene is known, and, if so, details of any secondary effects that could result from the integration, or further integration, at the site.

**1.3 Additional information — GMO that is a whole plant, or is to be used in conjunction with a whole plant**

If a Division 3 application relates to a GMO that will be a whole plant, or is to be used in conjunction with a whole plant, the following additional information is required for the application:

- (a) a statement on whether the parent organism is a weed or closely related to plants that are weeds and, if so, identification of the weeds that are closely related;
- (b) details of the stage of development that plants used in the proposed dealing, or dealings, will be allowed to reach;
- (c) details of the method that will be used to dispose of plants used in the proposed dealing or dealings;
- (d) a statement on whether soil, or soil substitute, will be used as the growing medium for the plants, and, if so, details of how that medium will be subsequently sterilised or disposed of.



**1.4 Additional information — GMO that is an animal, or is to be used in connection with an animal**

If a Division 3 application relates to a GMO that will be an animal, or that is to be used in connection with an animal, the following additional information is required for the application:

- (a) details of the number of:
  - (i) GM animals to be involved in the proposed dealing or dealings; and
  - (ii) other animals to be involved;
- (b) details of proposed arrangements:
  - (i) for breeding the animals; or
  - (ii) for ensuring that the animals do not breed;
- (c) details of how the animals will be able to be readily identified (for example, the use of labels on cages or, for larger animals, branding or tattooing).

**1.5 Additional information — GMO that is for use in clinical trials with human beings**

If a Division 3 application relates to a GMO that will be used in a clinical trial with a human being (as a vaccine or, in a gene therapy trial, as a vector), the following additional information is required for the application:

**1.5.1 Information about the purpose of the trial**

- (a) details of the disease to be treated, or prevented, by use of the GMO;
- (b) details of the host range of the parent organism from which the vaccine or vector is constructed.

**1.5.2 Information about the vaccine or vector**

- (a) details of the potential for the genetic material of the vaccine organism or gene therapy construct to become incorporated in whole, or in part, into the genome of any cells of a treated person;
- (b) details of the factors that prevent multiplication or spread of the vaccine organism or the vector in a treated person;

- (c) details of the period over which the GMO will be detectable in a person, or his or her excretions;
- (d) if the GMO is a defective virus, details of its potential for acquiring the capacity for viral replication by complementation or recombination with intracellular viruses;
- (e) details of any deleterious effects the GMO may have on a pregnant person;
- (f) a statement on whether the GMO has a teratogenic effect on a foetus at any stage of gestation and, if so, details of the effect;
- (g) a statement on whether the use of the GMO is likely to preclude its use for vaccination against other diseases subsequently;
- (h) a statement on whether the GMO produces spores;
- (i) a statement on whether the viability of the GMO is compromised by desiccation;
- (j) a list of sterilising and anti-microbial agents (if any) that are active against the GMO;
- (k) a statement on whether the GMO is susceptible to ultraviolet or ionising radiation.

1.5.3 *Information about the effect of the GMO on the environment*

- (a) details of:
  - (i) the potential for the GMO to spread from persons to whom the GMO has been administered to other persons or to other species; and
  - (ii) if the potential exists, the likely mechanism and frequency of such spread;
- (b) a statement on whether a person who undergoes the treatment could be more susceptible to an adverse outcome because of:
  - (i) the state of health of the person at the time of treatment (for example, the person presents with immunosuppression or superimposition of disease); or
  - (ii) other treatments, such as drugs;

- (c) details of the potential for the GMO to be disseminated into the environment through human waste during or after the trial;
- (d) details of proposed methods for disposing of waste containing the GMO;
- (e) a statement on whether, at the end of the trial, live GMOs will be carried by a person to whom the GMO has been administered and, if so, details of:
  - (i) the potential for their dissemination through family contact, or to the general population; and
  - (ii) measures intended to be taken to minimise the potential for dissemination; and
  - (iii) the potential for the organisms to cross the placenta of a pregnant person or animal.

*Note* For persons relying on National Health and Medical Research Council funding, additional requirements may apply (through the Gene and Related Therapies Research Advisory Panel) to dealings of the kind to which this item applies.

## 1.6 Supporting information to be given by IBC

Information required for a Division 3 application includes the following information to be given by an Institutional Biosafety Committee (*IBC*):

- (a) confirmation that the information given to the Regulator by the applicant has been checked by the IBC and found to be complete;
- (b) confirmation that the IBC considers that personnel intended to be involved in dealing with the GMO or GMOs have adequate training and experience for the task;
- (c) a statement that the IBC has evaluated the proposed project, and that includes the following details:
  - (i) the date of the evaluation;
  - (ii) the full name of the IBC;
  - (iii) the name and contact details of the chairperson and of the secretary of the IBC;
- (d) a copy of the evaluation report, prepared in accordance with any guidelines issued by the Regulator;

- (e) a statement that the IBC is established in accordance with the Regulator's guidelines under section 98 of the Act.

*Note* If the applicant is an accredited organisation, the IBC giving the information could be an IBC established by that organisation.

## **Part 2 Dealings involving an intentional release of a GMO into the environment (Division 4 of Part 5 of the Act)**

### **2.1 Information to be given by all applicants**

For an application to which Division 4 of Part 5 of the Act applies (a *Division 4 application*), the following information is required:

#### **2.1.1 General information**

- (a) details of the name, address, telephone number and other contact details, of applicant;
- (b) details of the name, position within the organisation and contact details, of applicant's project supervisor for the proposed dealing, or dealings, with a GMO, or GMOs;
- (c) title of the project involving the proposed dealing or dealings;
- (d) description of the GMO or GMOs;
- (e) description of the proposed dealing, or dealings, in terms of paragraph 40 (4) (a), (b) or (c) of the Act, as applicable;
- (f) description of the aims and purposes of the proposed dealing, or dealings;
- (g) identification of the person, persons or class of persons, intended to be authorised to undertake the dealing, or dealings;
- (h) the proposed date of commencement, and proposed date of completion, of the dealing or dealings.

#### **2.1.2 Risk assessment information – the parent organism**

- (a) details of the species to be released including, if relevant, information about the strain, cultivar etc;

- (b) an assessment of whether the parent organism is capable of causing disease or other ill-health in people, plants or animals and, if so, details of the possible effects;
- (c) details of the natural habitat of the parent organism, and its range;
- (d) details of the location where the parent organism was originally isolated for the purpose of the proposed dealing or dealings;
- (e) details of the distribution of the parent organism, and closely related organisms, in Australia;
- (f) a statement on whether the parent organism, or a closely related organism, is present at or near the site of the proposed release and, if so, details of the population or populations;
- (g) a statement on whether the parent organism is exotic in Australia;
- (h) details of any known predators, or parasites, of the parent organism in Australia.

### 2.1.3 *Risk assessment information – the GMO*

- (a) details of the origin of the DNA to be inserted;
- (b) if the inserted DNA will come from an organism that causes disease or other ill-health in humans, animals, plants or fungi, details of the effects;
- (c) details of the genetic modification that will be made, including details of the steps to be undertaken in its construction;
- (d) details of the stability of the genotype of the GMO or GMOs, including a statement on whether it has a potentially unstable genotype;
- (e) details of the extent to which the genetic modification has been characterised (that is, the DNA sequenced, and the potential gene products understood);
- (f) details of the intended location of the inserted DNA in the final construct, and the number of copies that will be present;

- (g) details of the markers or sequences that will enable the GMO or GMOs to be identified in the laboratory and under field conditions;
- (h) details of the type of vector to be used in the transfer (including a description of the vector), showing the position of the inserted DNA and any other control sequences or markers in the vector;
- (i) details of whether the vector has the ability to transfer to other hosts and, if so, details of the host range;
- (j) details of whether the recombinant vector will be present in the final construct and if not, how it will be removed;
- (k) if no vector will be involved, details of how the DNA will be introduced and how many copies of the gene will be inserted;
- (l) details of how the modification will change the phenotype of the organism to be released, including information to demonstrate the effect of the modification;
- (m) details of secondary genetic effects that may be anticipated;
- (n) a statement on whether the site, within the host genome, of integration of the resultant transgene is known;
- (o) details of the intrinsic genetic features, if any, of the GMO or GMOs that will regulate survival in the environment, including a statement on how stable those features are;
- (p) details of the genetic changes, if any, that will be included in the GMO or GMOs to limit or eliminate any capacity to reproduce or transfer genes to other organisms.

*2.1.4 Risk assessment information – proposed dealing with the GMO*

- (a) a description of the proposed dealing, or dealings, with the GMO or GMOs, including a description of the proposed intentional release into the environment;
- (b) a statement of:
  - (i) the proposed date or dates for the intentional release into the environment; or
  - (ii) if release is to occur over a number of days, the proposed commencement and completion dates;

- (c) a statement of the number of GMOs to be released;
- (d) a statement of the number of releases of the GMO that are proposed;
- (e) details of:
  - (i) the number of sites for proposed release; and
  - (ii) the area of land to be used; and
  - (iii) the location of the proposed release or releases, including identification of the local government area in which any release will take place and the geographical location, grid references and GPS coordinates of the site or sites;
- (f) details of the reasons for the choice of location or locations for the releases or releases;
- (g) details of how the GMO or GMOs will be released;
- (h) details of the methods to be used to test for batch to batch consistency, if large scale production is required to produce GMOs for release;
- (i) details of the measures that have been taken, or will be taken, in the production process to ensure quality and purity of GMOs intended to be released;
- (j) details of the arrangements for conducting any other dealings in association with the proposed release, such as importation of a GMO and transportation of a GMO to or from a release site;
- (k) details of proposed uses of the GMO or GMOs, or of things derived or produced from the GMO or GMOs, following release into the environment;

*Examples*

1. Collecting field trial material for laboratory analysis.
  2. Giving GM product to animals as stockfeed.
- (l) details of all previous applications (whether successful or unsuccessful) made under the Act, or to the Genetic Manipulation Advisory Committee, in relation to a proposed dealing with the GMO or GMOs, setting out in relation to each:
    - (i) any reference number given to the application by the Regulator or the Genetic Manipulation Advisory Committee; and

- (ii) the date of the application; and
- (iii) the name of the applicant's project supervisor, or intended supervisor.

2.1.5 *Risk assessment information – interaction between GMO and the environment*

- (a) a statement on whether release of a proposed GMO could prejudice any beneficial function of the parent organism in the environment;
- (b) on the basis of contained experiments, details of:
  - (i) the survival times of the GMO in habitats relevant to the release; and
  - (ii) the growth rate (or generation time) of the parent organism and GMO in the ranges of environmental conditions characteristic for the place and date of release; and
  - (iii) the frequency of reversion or loss of the genetic change;
- (c) details of the capability of the GMO to disperse from the release area or areas, and, if any, the dispersal mechanism;
- (d) a statement on whether the GMO is likely to be able to establish in the environment outside the release site or sites;
- (e) a statement on whether the GMO will be able to form long-term survival structures, such as seeds or spores;
- (f) a statement on whether the inserted genetic trait will be able to be transferred to other organisms found at the release site and surrounding environment and, if so, details of:
  - (i) the organisms the trait can be transferred to and the frequencies at which it can be transferred, including information about the species that have been tested for transfer and the rationale for selecting the test species; and
  - (ii) the transfer mechanisms involved; and
  - (iii) the techniques that have been used to demonstrate transfer; and



- (iv) any possible adverse effects of the transfer, including:
  - (A) any advantage that affected organisms are likely to have over members of the species that do not contain the transgene; and
  - (B) environmental risks posed by such an advantage;
- (g) a statement on whether interactions between pathogens and the transgene are possible (for example, gene silencing) and, if so, details of:
  - (i) the incidence and distribution of relevant pathogens; and
  - (ii) possible effects of interaction;
- (h) a statement on whether the GMO is likely to show any competitive advantages over its unmodified parent in mixed populations under the conditions at the release site or sites, and, if so, details of the nature of the advantages;
- (i) a statement on whether the modified trait will confer a selective advantage on the GMO under certain conditions and, if so, details of the conditions, including data on growth rates with and without selection pressure;
- (j) details of features of the physical environment of the release site or sites, particularly features that may minimise or exacerbate any undesirable effects of the GMO;
- (k) details of the proximity of the release site, or sites, to population centres, centres of agricultural activity, or the habitat of biota that might affect, or be affected by, the proposed release;
- (l) a statement on whether the GMO is expected to remain in the environment after release and, if so, details of:
  - (i) the period of time; and
  - (ii) any environmental risks posed by the GMO during that period;
- (m) details of any other environmental risks that may be posed by the GMO.

*2.1.6 Risk assessment information – risks GMO may pose to the health and safety of people*

- (a) details of any allergens or toxins that may be expressed by the proposed GMO that are not found in the parent organism;
- (b) details of any pathogenic properties in the GMO that are not found in the parent organism;
- (c) details of any occupational health and safety risks to personnel dealing with the GMO and safety risks to the wider community.

*2.1.7 Risk management information*

- (a) details of proposed measures for monitoring any risks posed by the proposed GMO, including monitoring for:
  - (i) the survival or presence of the GMO, or transferred genetic material, beyond the proposed release site or sites, including specificity, sensitivity and reliability of detection methods; and
  - (ii) impacts on the characteristics, or abundance, of other species; and
  - (iii) transfer of the introduced gene to other species; and
  - (iv) any other hazards or deleterious effects;
- (b) details of proposed measures for limiting the dissemination or persistence of the GMO, or its genetic material, in the environment;
- (c) details of the methods that will be used to minimise the effects of any transfer of the modified genetic trait to other organisms;
- (d) details of the specific experimental methods proposed for detecting the presence of the GMO, or transferred genetic material, in the recipient organism;
- (e) details of proposed measures for disposing of:
  - (i) the GMO when the release is complete; and
  - (ii) any waste deriving from the GMO;

- (f) details of proposed release-site supervision procedures and any safety procedures to be undertaken by staff, including a description of procedures for on-site supervision of the release if the release site is located at some distance from the location of the IBC;
- (g) details of proposed measures for:
  - (i) informing persons covered by the licence of any licence conditions; and
  - (ii) informing the public about the proposed dealing or dealings;
- (h) details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the Regulator;
- (i) details of any contingency measures that will be in place to rectify any unintended consequence if a hazard becomes evident during the course of the release;
- (j) details of ongoing monitoring to be undertaken after the release is completed.

#### *2.1.8 Information about previous assessments or approvals*

- (a) details of results of any applications made for approval of the GMO, or any derived GM products, by any other regulator in Australia or overseas, including information about conditions (if any) attaching to the approval;
- (b) details of any previous licence under the Act for dealing with the GMO, or of a notification of a dealing under the Act, from which the work in the present application has developed;
- (c) if the GMO has been previously released in Australia or overseas, details of any adverse consequences of the release, including identifying references and reports of assessments;
- (d) a list of Commonwealth and State government authorities that have been consulted about the proposed dealings with the GMO (including names of contact officers);
- (e) for an imported GMO — the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the Australian Quarantine and Inspection Service (AQIS).

**2.1.9** *Suitability of the applicant*

(if the information is not already provided to the Regulator for any other purpose)

- (a) details of qualifications, experience and proposed role of each person to be involved in the dealing or dealings;
- (b) a copy of the applicant's statutory annual report, or other information about the financial viability of the applicant;
- (c) for section 58 of the Act, details of any relevant convictions (within the meaning of that section) of the applicant or the project supervisor;
- (d) for section 58 of the Act, details of any failure to comply with:
  - (i) a provision of the Act or the Regulations; or
  - (ii) a condition of a licence or permit (within the meaning of paragraph 58 (1) (b) or 58 (2) (c) of the Act), particularly if resulting in a revocation or suspension;
- (e) details of any failure to comply with an advice to proceed issued by the Genetic Manipulation Advisory Committee;
- (f) details of applicant's capacity to manage any risks posed by the proposed dealing or dealings.

**2.2** **Additional information — GMO that is a plant**

If a Division 4 application relates to a proposed GMO that is a plant, the following additional information is required for the application:

**2.2.1** *Information about the use of the parent plant*

- (a) statement about whether the parent plant has an extended history of cultivation and safe use.

**2.2.2** *Information about any unintended pleiotropic effects*

- (a) details of undesirable effects on the parent plant that may result from expression of the transgene, or an associated insertion-related mutation, in the GMO (for example, reduced fertility, increased disease prevalence, production loss, grain shedding), including the likelihood of any such events.

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**2.2.3** *Information about pollen and cross-pollination*

- (a) details of the mechanism of pollen spread (by insect vectors or by other means) in the plant population;
- (b) details of pollen viability for the parent plant and the GMO;
- (c) details of any potential pollinators for the parent plant and the GMO, and their range and distribution in Australia;
- (d) quantitative data on successful cross-pollination between the parent plant, the GMO and its wild relatives;
- (e) if sexually compatible plants live near a site of the proposed release, details of the quantity and the chances for cross-pollination with the GMO;
- (f) if cross-pollination with the GMO were to occur, details of the likely resulting plants and an assessment of whether they would survive and compete well with unaffected plants.

**2.2.4** *Information about weeds*

- (a) details of members of the family of unmodified parent plants that are known to be weeds in any environment;
- (b) details of cross-pollination between the species to which the GMO belongs and relatives known to be weeds, including a copy of any peer-reviewed reports that support the information.

**2.2.5** *Information about the possible result of the imparted characteristics being integrated into other species*

- (a) a statement on whether the novel characteristics of the GMO could be integrated into other species and, if so, details of its potential to affect:
  - (i) the distribution and abundance of populations of the affected species; and
  - (ii) factors that normally control populations of the affected species in the environment (for example, pathogens, herbivory and physiological stress);
- (b) details of any other possible adverse consequences;

- (c) details of proposed measures to minimise the risk (for example, by imparting male sterility or other means of reproductive isolation).

**2.2.6** *Information about the seeds of the GMO*

- (a) a statement on whether the GMO proposed to be released will be allowed to set seed and, if not, whether setting seed is planned for a later release;
- (b) if the GMO is to be allowed to set seed — a statement on whether mature seed is expected to be shed (from, for example, an ear, capsule or pod), and, if so, an indication of the proportion of seed likely to remain in the environment following harvest;
- (c) a statement on whether the seed has the potential to be dispersed by natural mechanisms and, if so, details of the mechanisms;
- (d) details of the length of time the seeds will be capable of being dormant.

**2.2.7** *Information about whether the GMO can be dispersed by vegetative propagation*

- (a) a statement on whether the GMO proposed to be released can be dispersed by vegetative propagation and, if so, the possible mechanisms.

**2.2.8** *Information about whether the capacity of the GMO to add substances to, or subtract substances from, soil will change*

- (a) a statement on whether the novel characteristic of the proposed GMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such change.

**2.2.9** *Information about toxicity*

- (a) an assessment of whether there is any likelihood that the introduced trait could cause the proposed GMO to have greater toxicity (for animals, including human beings) than

would an unmodified plant and, if so, details of that likely effect;

- (b) an assessment of whether any products of the GMO could concentrate in the natural or human food chain to levels which become toxic, and available data (if any) on that subject;
- (c) an assessment of whether the biodegradability of the GMO will be different to that of the parent organism and, if so, details of the differences.

*2.2.10 Information about any secondary ecological effects that might result from the release*

- (a) an assessment of possible effects of the proposed release on:
  - (i) native species; and
  - (ii) resistance of insect populations to an insecticide; and
  - (iii) abundance of prey or parasites.

*2.2.11 Information about resistance of the GMO to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)*

- (a) for a GMO that, as a result of the modification, will have resistance to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction) — details of any environmental risks related specifically to that resistance.

*2.2.12 Information about resistance of GMO to a biological agent*

- (a) for a GMO that, as a result of the modification, will have resistance to a biological agent (for example, an insect or a fungal disease) — details of any environmental risks related specifically to that resistance.

**2.3 Additional information — GMO that is a micro-organism (not living in or on animals and not a live vaccine)**

If a Division 4 application is in relation to a proposed GMO that is a micro-organism:

- (a) including a micro-organism associated with plants, and a micro-organism that might be applied to modify the physical or chemical environment (for example, to modify soil properties); but
- (b) not including a micro-organism living in or on animals, or a micro-organism that is a live vaccine;

the following additional information is required for the application:

**2.3.1 *Information about GM micro-organisms associated with plants***

- (a) details of any partner species of plant, including information about the specificity of the interaction and the range of plant species with which the proposed GMO can interact;
- (b) an assessment of the effect of the proposed GMO on the partner plant species, and details of how it will be monitored;
- (c) an assessment of any secondary effects that the proposed GMO might have on the partner plant species;
- (d) an assessment of whether the modification is likely to cause any change to the range of host plant species susceptible to infection by the organism;
- (e) an assessment of the effect, if any, of the proposed GMO on the distribution and abundance of host plant species or other species with which the proposed GMO can interact;
- (f) an assessment of the effect the proposed GMO might have on insects, birds, animals or humans that may eat the plant.



**2.3.2** *Information if the parent organism has an extended history of use in agriculture*

- (a) if the parent organism has an extended history of use in agriculture, a description of the use.

**2.3.3** *Information if the GM micro-organism is associated with plant species that are food crops*

- (a) if the GM micro-organism is associated with plant species that are food crops, an assessment of whether the proposed GMO could affect the suitability of the resultant produce for consumption by animals or human beings and, if so, details of the effect.

**2.3.4** *Information about the impact of the GMO on soil and water*

- (a) details of the expected effects of the proposed GMO on local soil chemistry (for example, pH, mineral leaching and nutrient levels);
- (b) details of the possible effects of the proposed GMO on local water quality;
- (c) details of the effects the proposed GMO might have on soil organisms that are known to be beneficial to plants (for example, *Rhizobium*, *Azospirillum*, *Frankia* and mycorrhizal fungi) and that are likely to be in a release site.

**2.3.5** *Information about any interactions between the GMO and closely related micro-organisms*

- (a) details of any known interaction between the proposed GMO and closely related micro-organisms in any partner plant (if applicable) and in the environment of the release site.

**2.3.6** *Information about known genetic exchange between parent organism and plant pathogens*

- (a) details of any known exchange of genetic material between the parent organism and plant pathogens.

### 2.3.7 *Other information*

- (a) information about the expected survival and dispersal of the proposed GMO, including dispersal in natural waters, soil and on other natural surfaces;
- (b) a statement about whether the proposed GMO will produce spores;
- (c) a statement about whether the proposed GMO will be resistant to desiccation;
- (d) a list of sterilising and anti-microbial agents (if any) that are expected to be active against the proposed GMO;
- (e) a statement about whether the proposed GMO will be susceptible to ultraviolet or ionising radiation.

## 2.4 **Additional information — GMO that is a micro-organism that lives in or on animals**

If a Division 4 application is in relation to a proposed GMO that is a micro-organism living in or on animals (including an organism such as gut biota living in larger hosts, and a micro-organism applied externally to an animal (for example, bacteria to prevent fleece rot)), the following additional information is required for the application:

### 2.4.1 *Information about the impact of the GMO on the host*

- (a) identification of the animal host species;
- (b) a statement about whether the parent organism has an extended history of use in agriculture and, if so, details of the use;
- (c) an assessment of any new capacity the proposed GMO will provide for the host species (for example, ability to degrade plant or pasture toxins);
- (d) an assessment of whether the competitive advantage, ecological fitness, biology or distribution, of the host will be altered, and relevant data (if any) on the subject;
- (e) details of any secondary effects expected to result from the introduction of the proposed GMO into or onto the host (for example, information about any possibility of the genetic insert being transferred to other organisms in the host, or to host cells).

**2.4.2** *Information about the impact of the GMO on the environment (particularly the impact on other animals, plants, soil and water)*

- (a) any evidence that the proposed GMO might be capable of establishing in, or on, other animals, including feral animals;
- (b) any evidence of other likely effects (including secondary effects) on other plants or animals in the agricultural and natural environments;
- (c) if the proposed GMO will establish in an animal, information about whether the GMO will be excreted or otherwise leave the animal and, if so, the time period that it is expected the GMO can survive outside the animal;
- (d) an assessment of the possible effects of the GMO on local water quality.

**2.4.3** *Other information*

- (a) a statement about whether the proposed GMO will produce spores;
- (b) a statement about whether the proposed GMO will be resistant to desiccation;
- (c) a list of sterilising and anti-microbial agents (if any) that are expected to be active against the proposed GMO;
- (d) a statement about whether the proposed GMO will be susceptible to ultraviolet or ionising radiation.

**2.5** **Additional information — GMO that is a live vaccine for use in animals**

If a Division 4 application is in relation to a GMO that is a live vaccine for use in animals, the following additional information is required for the application:

**2.5.1** *Information about the purpose of the vaccine*

- (a) identification of the disease to be treated, or prevented, by use of the vaccine;
- (b) identification of the host species on which the vaccine is to be used;

- (c) details of the host range of the parent organism from which the vaccine is constructed;
- (d) details of the level, and duration, of immunity produced in the host species after administration of the vaccine.

#### 2.5.2 *Information about the vaccine*

- (a) an assessment of the potential for the genetic material of the vaccine organism to become incorporated in whole, or in part, into the genome of any cells of the vaccinated host;
- (b) an assessment of the period over which the vaccine GMO will be detectable in a test animal, or its excretions;
- (c) if the GMO is a viral vaccine, information about the potential for the nucleic acid of the virus in the vaccine to be rescued, or to be restored to wild type, by recombination or complementation with intracellular viruses;
- (d) details of any deleterious effects the vaccine GMO may have on a pregnant animal;
- (e) a statement on whether the vaccine GMO has a teratogenic effect on a foetus at any stage of gestation;
- (f) a statement on whether the use of the vaccine GMO is likely to:
  - (i) preclude its use for vaccination against other diseases subsequently; or
  - (ii) affect its usefulness for other vaccinations;
- (g) a statement on whether the vaccine GMO produces spores;
- (h) a statement on whether the vaccine GMO is resistant to desiccation;
- (i) a list of sterilising and anti-microbial agents (if any) that are active against the GMO;
- (j) a statement on whether the GMO is susceptible to ultraviolet or ionising radiation.

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**2.5.3** *Information about the effect of the GMO on the environment*

- (a) details of:
  - (i) the potential for the vaccine GMO to spread from vaccinated to unvaccinated animals or to other species (including human beings); and
  - (ii) if the potential exists, the likely mechanism and frequency of such spread;
- (b) an assessment of whether the susceptibility of the host to the vaccine organism could be affected by:
  - (i) the state of the host at the time of vaccination (for example, immunosuppression, or superimposition of other disease); or
  - (ii) other treatments, such as drugs;
- (c) details of proposed methods for disposing of waste containing vaccine GMO;
- (d) details of the intended fate of vaccinated animals at the end of the trial;
- (e) information about whether live vaccine organisms will be carried by an animal at the end of the trial and, if so:
  - (i) the potential for dissemination of the live vaccine organisms through the animal's family contact, or to the general population of the species; and
  - (ii) measures intended to be taken to minimise the potential for dissemination; and
  - (iii) the potential for the organisms to cross the placenta of a pregnant animal.

## **2.6 Additional information — GMO that is a vertebrate animal**

If a Division 4 application is in relation to a GMO that is a vertebrate animal (other than aquatic organisms), the following additional information is required for the application:

### *2.6.1 Information about the effects of the GMO on the environment*

- (a) information about the likelihood of any unintended effect on an animal resulting from the release;
- (b) information about any intended gains that are directly linked to changes in other characteristics of the subject species.

### *2.6.2 Information about any effects the expression of the modified trait might have on the animal*

- (a) information about expected effects on the physiology, behaviour and reproduction of the animal or animals.

### *2.6.3 Information about future dealings with the GMO*

- (a) a statement on whether an animal in the experiment is intended to be allowed to breed and, if not, whether breeding is planned in the future;
- (b) a statement on whether the proposed arrangements for handling any offspring are the same as those for the experimental animal or animals, and, if not, the proposed different arrangements.

### *2.6.4 Information about feral populations of subject species, if any, that exist in Australia or that may be established*

- (a) details of any agricultural, environmental or disease-control problems caused by feral populations of the subject species;
- (b) details of any experimental work that has been done on expression of the novel genetic material in feral animals (such as cross-breeding of GMOs with captive feral animals), and the results of such work;

- (c) an assessment of the likelihood of the novel genetic material entering the feral gene pool (for example, by interbreeding with modified farm animals);
- (d) an assessment of the effect that the entry of the novel genetic material into a feral gene pool might have:
  - (i) on the distribution and abundance of the feral population; or
  - (ii) on the ability of the feral population to cause agricultural or environmental problems; or
  - (iii) in contributing to the spread of infectious disease;
- (e) if no feral population exists in Australia, information about:
  - (i) the likelihood of the imparted characteristic enhancing the ability of the species to establish feral populations; and
  - (ii) if there is a likelihood, the arrangements in place to prevent this from occurring.

*2.6.5 Information about the capacity of the GMO to interbreed*

- (a) details of the capacity of the GMO to interbreed with any species native to, or currently present in, Australia.

*2.6.6 Information about requirements for optimal expression of the introduced trait*

- (a) details of the management procedures and environmental factors, if any, that would be required for optimal expression of the introduced trait or traits.

*Note* All work involving animals should be conducted according to the NHMRC *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, under which it requires review by an Institutional Animal Ethics Committee and by the relevant authority administering State animal welfare legislation.

## **2.7 Additional information — GMO that is an aquatic organism**

If a Division 4 application is in relation to a GMO that is an aquatic organism (for example, fish, crustaceans and molluscs), the following additional information must be included:

### *2.7.1 Information about effects of the GMO on the environment*

- (a) a statement on whether the GMO could produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites or predators and, if so, the likely effect;
- (b) details of any unintended effects that may result from the release;
- (c) a statement on whether the expression of the modified gene is expected to be directly linked to undesirable changes in other characteristics of the subject organisms (for example, a decrease in nutritional value);
- (d) information about:
  - (i) whether the modified genetic material can be transmitted to any other species; and
  - (ii) if so, the expected mechanism of transfer, the likely affected species and any likely consequences.

### *2.7.2 Information about any impact on natural populations*

- (a) information about whether natural populations of the parental organism, or a closely related species, exist in Australia (including in rivers, lakes, dams or coastal waters) and, if so, details about any problems the natural populations cause with other organisms;
- (b) if no natural populations of the organism to be modified exist in Australia, information about the potential for the modified traits to enhance the ability of the species to establish populations in aquatic habitats;
- (c) information about the results of any experimental work that has been done on phenotypic expression of the modified genetic material in naturally occurring organisms (such as cross-breeding of GMOs with wild or farmed stocks);



- (d) an assessment of the likelihood of the modified genetic material entering the gene pool of natural populations;
- (e) information about any impact the entry of the modified genetic material into the gene pool of a natural organism could have on:
  - (i) the distribution and abundance of the organism; or
  - (ii) associated aquatic farms; or
  - (iii) the environment; or
  - (iv) public health;
- (f) information about mechanisms intended to be used to prevent dispersal of the GMO into other ecosystems.

### 2.7.3 *Information about future dealings with the GMO*

- (a) a statement about whether an organism in the experiment is intended to be allowed to breed and, if not, whether breeding is planned in the future;
- (b) a statement about whether the proposed arrangements for handling any offspring are the same as those for the experimental organisms and, if not, the proposed different arrangements.

## 2.8 **Additional information — GMO that is an invertebrate animal**

If a Division 4 application is in relation to a GMO that is an invertebrate animal, the following additional information must be included:

- (a) information about the effect the GMO might have on the food chain;
- (b) information about the potential for the GMO to produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites or predators;
- (c) information about other unintended effects that may result from the release;
- (d) a statement on whether the GMO will be fertile and, if not, whether it is intended to use fertile organisms in later releases;

- (e) information about whether populations of the parental organism, or a closely related species, exist in Australia and, if so, any environmental or public health problems, or benefits, caused by the populations;
- (f) information about:
  - (i) whether the modified, genetic material can be transmitted by means other than by reproduction normal for the species; and
  - (ii) if so, the likelihood of that genetic material entering gene pools of natural populations;
- (g) information about:
  - (i) whether the modified, genetic material can be transmitted to any other species; and
  - (ii) if so, the expected mechanism of transfer, and the likely affected species;
- (h) information about any experimental work that has been done on the phenotypic expression of the novel genetic material in other genetic backgrounds (such as cross-breeding of modified strains with wild or caught stock);
- (i) information about the effect, on the distribution and abundance of the natural populations of the organism, of the entry of the novel genetic material into the gene pool of those populations;
- (j) details of the mechanisms proposed to be used to prevent dispersal of the GMO into other ecosystems.

## **2.9 Additional information — GMO that is to be used for biological control**

If a Division 4 application is in relation to a GMO that is to be used for biological control, the following additional information must be included:

### *2.9.1 Information about the expected interaction between the GMO and the species targeted for biological control*

- (a) the name of the species targeted for biological control;
- (b) details of any direct effects the parent organism has on the target species;

- (c) details of any direct effects the GMO is expected to have on the target species;
- (d) details of how the GMO is intended to be transferred from one target organism to another, and what factors affect the transferability;
- (e) details of the genetic response that may be invoked in populations of the target organism as a result of the use of the GMO (for example, increased resistance to the modified organism), and the expected evidence for the response.

*2.9.2 Information on the possible effects of the GMO on non-target organisms*

- (a) details of the host range of the GMO, and details of any difference between that host range and the host range of the parent organism;
- (b) a list of the non-target organisms that have been tested for susceptibility to the GMO, and the rationale for the choice of species tested;
- (c) if the modified traits can be transmitted to other organisms that are likely to be in the environment, details of any effects those other organisms are likely to have on non-target species.

*2.9.3 Information on other possible effects of the GMO on the environment*

- (a) a statement about the secondary effects that can be envisaged on competitors, predators, prey or parasites of the target species;
- (b) an assessment of the consequence of the removal, or reduction, of the target species on the management of agriculturally significant plants or farm animals;
- (c) details of any predicted change in the ecosystem resulting from a reduction in the population of the target organism;

- (d) information about:
  - (i) whether the GMO produces metabolites that may have deleterious effects on other organisms, including human beings:
    - (A) directly; or
    - (B) indirectly, through concentration in the food chain; and
  - (ii) if so, the likely effect.

## **2.10 Additional information — GMO that is to be used for bioremediation**

If a Division 4 application is in relation to a GMO that is to be used for bioremediation, the following additional information must be included:

### **2.10.1 *Information about the expected interaction between the GMO and the target substrate for bioremediation***

- (a) identification of the target substrate for bioremediation;
- (b) details of the effect the parent organism has on the target substrate;
- (c) details of the effect the GMO is expected to have on the target substrate;
- (d) a list of the substances other than the target substrate that can be metabolised by the GMO and that cannot be metabolised by the parent organism.

### **2.10.2 *Information about the GMO and its impact on the environment***

- (a) a statement about whether the GMO will be self-sufficient if added to the contaminated site or whether additional measures may be required (for example, provision of supplementary nutrients and growth factors, or other environmental modifications);
- (b) a list of any metabolites produced by the GMO that may have deleterious effects on other organisms:
  - (i) directly; or
  - (ii) indirectly, through concentration in the food chain;

- (c) details of effects the GMO might have on water, air or soil quality;
- (d) details of effects the GMO might have on organisms that ingest it;
- (e) a statement on whether the GMO will be dispersed from the site of application and, if so, the proposed mechanisms involved and the likely consequences.

## 2.11 Additional information — GMO intended to be used as food for human or vertebrate animal consumption

If a Division 4 application is in relation to a GMO that is intended to be developed for use as a food for consumption by human beings or animals, the following additional information must be included:

- (a) details of:
  - (i) whether the parent organism or the donor organism is of a kind already in use as a food for consumption by human beings or animals, or used in the production of such a food; and
  - (ii) whether any processing is needed, or is commonly applied, before consumption;
- (b) details of any metabolites produced by the GMO that may have adverse effects on the consumer (human or animal), including available data on toxicology, allergenicity and other possible adverse effects;
- (c) details of any products of the GMO that are expected to concentrate in the food chain to levels which may become toxic;
- (d) details of any expected changes to the nutritional quality of such food as a result of the genetic modification;
- (e) a statement on whether the GMO is a major component of such food as consumed, or a minor component (for example, yeast cells in beer).

*Note* For a food for human consumption that contains GMOs or GM products, see also the assessment requirements under the *Australia New Zealand Food Authority Act 1991*.

## 2.12 Supporting information to be given by IBC

Information required for a Division 4 application includes the following information to be given by an Institutional Biosafety Committee (**IBC**):

- (a) confirmation that the information given to the Regulator by the applicant has been checked by the IBC and found to be complete;
- (b) confirmation that the IBC considers that personnel intended to be involved in dealing with the GMO or GMOs have adequate training and experience for the task;
- (c) a statement that the IBC has evaluated the proposed project, and that includes the following details:
  - (i) the date of the evaluation;
  - (ii) the full name of the IBC;
  - (iii) the name and contact details of the chairperson and of the secretary of the IBC;
- (d) a copy of the evaluation report, prepared in accordance with any guidelines issued by the Regulator;
- (e) a statement that the IBC is established in accordance with the Regulator's guidelines under section 98 of the Act.

*Note* If the applicant is an accredited organisation, the IBC giving the information could be an IBC established by that organisation.

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### Note

1. Notified in the *Commonwealth of Australia Gazette* on / 2001.

31 May