Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

Application for a licence

for dealings with a non-plant GMO involving intentional release of the GMO into the environment (DIR)

Title of the project:	Enter title
Applicant organisation name:	Enter name
Accreditation number: (If the organisation is accredited by the Gene Technology Regulator)	Enter number

Is this application accompanied by an application for a declaration that certain information be treated as Confidential Commercial Information (CCI)?

☐Yes ☐No

If the CCI is covered by previous CCI application(s), please provide the CCI or DIR application number(s) here:

the relevant CCI application number(s): Enter numbers

and the DIR application number(s): Enter number

If any information provided is covered by previous CCI declaration(s) and can now be made available to the public, please contact the Office of the Gene Technology Regulator to have the declaration revoked.

Time taken to complete this form: Enter hours Enter minutes

Information for applicants

We encourage prospective applicants to contact the Office of the Gene Technology Regulator (OGTR) before submitting an application to advise you in selecting the appropriate application form and discuss information requirements. **This is particularly important if the parent organism is not present in the Australian environment.** You can call (1800 181 030) or email.

What is this application form for?

This form must be used for applications for a licence for dealings (activities) with a GMO involving intentional release (DIR) of the GMO into the environment under the *Gene Technology Act 2000* (the Act). There are separate forms if you wish to apply for a licence to conduct dealings involving GM plants.

What information do you need to provide?

This application for a licence must contain correct and adequate answers. You must answer each question unless otherwise instructed.

The Regulator is not required to consider applications for a licence which do not contain the information specified.

If you wish to protect any information on this form from public disclosure, you must also fill out an *Application for Declaration that specified information is Confidential Commercial Information (CCI)*. Please submit it together with this DIR licence application form. Further explanatory material with respect to the information requirements associated with a CCI application is provided on the *Application for Declaration that specified information is CCI* form.

What will we use the information provided in this form for?

We will use the information in the application to prepare a Risk Assessment and Risk Management Plan (RARMP) in relation to the proposed activities. The Regulator's decision whether or not to issue a licence, and conditions to impose if a licence is issued, is based upon the RARMP.

Information in this application, including all attachments, may be released to the public (refer to section below 'What else do you need to know?' for further information).

What is the application fee for a DIR licence application?

There is currently no application fee.

How should you fill out this form?

- We prefer you sending your application electronically in a searchable format.
- Ensure you answer each relevant question in sufficient detail. Not providing the required information could delay a decision, or the Regulator may not consider your application (section 43 of the Act).
- Ensure you answer each question to the best of your knowledge. Deliberately providing false or misleading information is a punishable offence (section 192 of the Act).
- Ensure you answer each question with adequate supporting material. Scientific information should be comprehensive and supported by whatever data and references are available. We may ask you to provide electronic or hard copies of journal publications and unpublished information.
- Do not repeat information. If necessary, refer to your answer to other questions.
- Contact us if you have any questions or would like our comments on a draft application.

How can you submit this form?

Once you have obtained the relevant signatures, you can submit a hard copy or an electronic copy by:

- **email** to: ogtr.applications@health.gov.au
- **by mail** to: Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra, ACT, 2601.

Please keep a copy of the application for your records.

You should note that if you email an application containing sensitive information (such as CCI), it will be transmitted via an unclassified internet connection and will not be protected in the process. Within a

reasonable time of receipt of the application, staff in the OGTR will securely store the sensitive information as appropriate. If you wish to make alternative arrangements to securely transmit CCI information, please contact this office.

What will happen after you have submitted the application?

We will acknowledge receipt of the application by email and assign it an OGTR reference number. Please cite this reference number whenever you contact us regarding the application.

Please contact us if we have not confirmed receipt within two weeks of submission.

We will notify the public about the application and then prepare a RARMP, including proposed licence conditions. This document will be released for expert and public consultation. You will also be invited to comment, particularly on whether you would be able to comply with the proposed licence. We will finalise the RARMP considering the comments received. It then forms an important part for the basis on which the Regulator will decide whether or not to issue a licence. Once issued, a licence is a legally binding instrument and penalties may apply for breaches of conditions.

How long will it take the Regulator to decide whether or not to issue a licence?

The Regulator must make a decision to issue, or to refuse to issue, a licence for a limited and controlled release application under Section 50A of the Act within 150 working days, or 170 working days if significant risk is identified (weekends and ACT public holidays are excluded). The Regulator must make a decision for all other DIR applications within 255 working days.

We may ask you for additional information in relation to your application. Any days on which the Regulator cannot proceed with decision making while awaiting requested information do not count for purposes of determining the end of the decision-making period. The Regulator may cease to consider your application if you fail to provide requested information within the specified timeframe.

Will the Regulator need additional information after deciding to issue a licence?

Licence conditions require a licence holder to:

- provide details of any adverse or unintended effect that becomes evident during the release
- supply a contingency plan to be implemented in the event that the GMO is found outside of permitted areas
- detail a detection method specific for the GMO and introduced genetic modification and
- report annually in relation to permitted activities.

What else do you need to know?

The Regulator must provide a copy of a submitted DIR application to anyone requesting it (see section 54 of the Act). Any information in your application, including personal information in Parts 1, 2, 5 and 6, may be made public, except:

- information declared or under consideration as confidential commercial information (CCI) by the Regulator (see section 185 of the Act)
- information in the application about relevant convictions (see section 58 of the Act)
- information subject to the Privacy Act 1988.

Part 1:Contact Details for the Application

Details of the person the OGTR can contact regarding this application.

Personal title, e.g. Ms/Mr/Dr:	Enter title
Surname:	Enter name
First name:	Enter first name
Phone number:	Enter phone number
Mobile number:	Enter mobile number
Fax number:	Enter fax number
Email address:	Enter email address
Job title:	Enter job title
Street number and name:	Enter street number and name
Town/city/locality:	Enter town/city
State/territory:	Enter state/territory
Postcode:	Enter postcode
Country:	Enter country
Postal address, if different:	Enter postal address

Part 2: Project Supervisor

Personal title, e.g. Ms/Mr/Dr:	Enter title
Surname:	Enter surname
First name:	Enter first name
Preferred first name, if different:	Enter preferred first name
Phone number:	Enter phone number
Mobile number:	Enter mobile number
Fax number:	Enter fax number
Email address:	Enter email address
Job title:	Enter job title
Street number and name:	Enter street number and name
Town/city/locality:	Enter town/city
State/territory:	Enter state/territory
Postcode:	Enter postcode
Country:	Enter country
Postal address, if different:	Enter postal address
Relevant qualifications and skills:	Enter relevant qualifications and skills

Part 3: Applicant Organisation type

3.1 This application is being made by:

☐a natural person, or

☐an organisation

3.2 Information about the applicant organisation type

If the application is by an organisation, indicate below which of the following best describes your organisation. You may need to tick more than one box.

Note: Your response to this question is necessary to determine whether the Regulator will issue the licence under Commonwealth legislation or under corresponding State law. If unsure you should seek legal or other advice which will accurately identify the legal status of the organisation.

a. For an organisation which is a constitutional corporation, ie a trading, foreign or financial corporation within the meaning of paragraph 51(xx) of the Constitution, is the organisation a:

☐Higher Education Institution

☐Hospital

☐Research Institute or similar

☐Commonwealth Authority which is a body corporate established under an Act and/or a company in which a controlling interest is held by the Commonwealth or a Commonwealth authority

☐State instrumentality which is a body corporate established under an Act and/or a company in which a controlling interest is held by that State or by a State instrumentality

☐Corporation which is none of the above? Please provide details.

Enter details.

b. For an organisation which is NOT a constitutional corporation, is the organisation a:

☐Higher Education Institution

☐Hospital

☐Research Institute or similar

☐Commonwealth Department

☐State Government Department

☐Organisation which is none of the above? Please provide details.

Enter details

Part 4: Suitability of the applicant

4.1 Has the applicant been convicted of an offence against a law of the Commonwealth, a State[1] or a foreign country which relates to the health and safety of people or the environment where the offence was committed within a period of ten years immediately before the making of the application for this licence and which was punishable on conviction by a fine of $5000 or more, or by a term of imprisonment of one year or more?

☐Yes ☐No

If Yes, provide details of:

- the Act the offence was committed under
- the date the offence was committed
- the date of the conviction
- the penalty which was imposed and
- why the Regulator should still consider the applicant suitable to hold a licence.

Enter details

4.2 If the applicant answered Yes to the preceding question and is a body corporate:

a. Was any person who is currently a director of the applicant also a director of the applicant at the time that the offence was committed?

☐Yes ☐No

If Yes, provide director's name.

Enter details

b. Was any person who is currently an officer or shareholder of the applicant, in a position to influence the management of the applicant, also such an officer or shareholder at the time that the offence was committed?

☐Yes ☐No

If Yes, provide details.

Enter details

[1] 'State' includes the Australian Capital Territory and the Northern Territory (Section 10 of the Act).

4.3 Has the applicant had a licence or permit (however described) revoked or suspended under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment?

☐Yes ☐No

If Yes, provide details.

Enter details

4.4 To the best of the applicant's knowledge, will the applicant be financially viable for the proposed duration of the licence?

☐Yes ☐No

If No, justify why the Regulator should consider the applicant suitable to hold a licence.

Enter details

4.5 What is the date of the applicant's latest financial statement?

Select date

4.6 Attach copies of the applicant's latest financial statement and either the audit findings or a statement from a director of the company (or a person otherwise authorised to make the statement) that the financial statement provided presents a true and fair view, in all material aspects, of the affairs of the applicant for the period covered by the statement.

The Regulator will not consider an application unless it is accompanied by the required financial information. If available, an electronic copy of the financial statement can be provided, eg by providing the URL for the statement on the internet.

Enter URLs or attachment numbers

4.7 What is the expected date of the applicant's next financial statement?

If the applicant's next financial statement is prepared prior to the Regulator reaching a decision on this application a copy of the financial statement must be sent to the OGTR as soon as it is available.

Select date

4.8 Is there any other information relevant to the above questions that may assist the Regulator in making a decision about the suitability of the applicant for a licence?

☐Yes ☐No

If yes, provide details.

Enter details

Part 5: Supporting Information from the Institutional Biosafety Committee (IBC) – not required for applications for commercial supply

This part must be completed by the IBC responsible for the Applicant Organisation if the application is for a limited and controlled release DIR (eg a trial).

Name of IBC:	Enter name
Name of IBC Chair:	Enter name
Phone number of the IBC: Chair	Enter phone no.
Fax number of the IBC: Chair	Enter fax no.
Email address of the IBC Chair::	Enter email
Date of IBC evaluation of this application	Select date

Name of IBC Primary Contact:	Enter name
Phone number of the IBC Primary Contact:	Enter phone no.
Fax number of the IBC primary Contact:	Enter fax no.
Email address of the IBC primary Contact:	Enter email

5.1 Has the information contained in this form been checked by the IBC and found to be complete?

☐Yes ☐No

Provide more detail, where appropriate.

Enter information

5.2 Does the IBC consider that the personnel intended to be involved in dealing(s) with the GMO(s) to have adequate training and experience for the task?

☐Yes ☐No

Provide more detail, where appropriate.

Enter information

5.3 When considering the information contained in this application, was the IBC constituted in accordance with the relevant provisions of the Regulator's *Guidelines for the Accreditation of Organisations*?

☐Yes ☐No

Provide more detail, where appropriate.

Enter information

Part 6: Declarations

Parts 5 and 6 must be completed after the applicant has completed all other Parts.

I DECLARE THAT:

- I am duly authorised to sign this declaration; and
- to the best of my knowledge, the information supplied on this form and any attachment(s) is not false or misleading.

CEO (or Delegate with Authority to Sign) of the Applicant Organisation

Print name:	Print name
Signature:	……
Job title:	Enter job title
Date:	Select date

Project Supervisor

Print name:	Print name
Signature:	……
Job title:	Enter job title
Date:	Select date

IBC Chair – not required for applications for commercial supply

Print name:	Print name
Signature:	……
Job title:	Enter job title.
Date:	Select date

Part 7: About the dealings with the GMO(s)

Before answering this Part the applicant is encouraged to familiarise themselves with 50A of the Act. Questions in Part 7 and 12 of this form that appear in ***italics and bold*** are the most important questions that relate to any proposed limits and controls for this application. Answers to these questions will be taken into account by the Regulator for purposes of deciding whether section 50A of the Act can apply to this application.

Title of project:	Enter title
Proposed date of commencement:	Select date
Proposed date of completion:	Select date
Description of proposed dealing(s) with the GMO(s), including a description of the proposed intentional release into the environment:	Enter description
Specify person, persons or class of persons intended to be authorised to undertake dealing(s) with the GMO(s):	Enter description
Description of purposes and aims of the proposed dealing(s): **Note:** The answer to this question is important for the Regulator to determine whether the principle purpose of the application is to conduct experiments. Please provide details of any proposed dealings for testing hypotheses, gaining scientific or technical knowledge or gaining data for regulatory purposes, or for product development or marketing.	Enter description

7.1 Will any of the proposed dealing(s) involve the intentional release of GMO(s) into the environment?

☐Yes ☐No

7.2 Is it the intention of the applicant that the dealing(s) to be undertaken will involve a limited and controlled release pursuant to section 50A of the Act?

☐Yes ☐No

7.3 Will any of the proposed dealings with GMOs involve the use of nanotechnology*, or inclusion or production of engineered nanomaterials?**

☐Yes ☐No

*** Nanotechnology** is engineering at the atomic or molecular level, involving the manipulation of matter at the nanoscale (generally accepted as 100 nanometres or less) to create new materials, structures and devices. For the purpose of this question, nanotechnology does not include standard techniques of molecular biology/gene technology.

**** Engineered nanomaterials** are materials designed at the molecular level to take advantage of novel properties which are generally not seen in their conventional counterparts.

The Australian Government has committed to taking a proactive approach in monitoring developments in nanotechnology so as to ensure the regulatory frameworks charged with protecting public health, safety and the environment keep pace with these changes.

Information about the dealings with the GMO(s)		**Attachment Number**
7.4	Details of: (i) the number of sites for proposed release; and (ii) the area of land to be used (if applicable); and (iii) the location of the proposed release(s), including identification of the local government area(s) in which any release will take place and the geographical location, grid references and GPS coordinates of the site(s)	
7.5	Details of the reasons for the choice of location(s) for the release(s)	
7.6	Details of the number of different types (events, lines, species, etc) of GMO(s) that will be released	
7.7	Details of how the GMO(s) will be released	
7.8	Details of the methods to be used to test for batch to batch consistency, if large scale production is required to produce the GMO(s) for release	
7.9	Details of the measures that have been taken, or will be taken, in the production process to ensure quality and purity of the GMO(s) intended to be released	
7.10	Details of the arrangements for conducting any other dealing(s) in association with the proposed release(s), such as importation of a GMO(s) and transportation of a GMO(s), to or from a release site(s)	
7.11	Details of proposed uses of the GMO(s), or of things derived or produced from the GMO(s), following release into the environment	

Part 8: Description of the GMO(s)

Information		Attachment Number
8.1	Details of the modified trait(s) and how the modification will change the phenotype of the organism(s) to be released, including information to demonstrate the effects of the modification(s)	
8.2	Identity of the gene(s) responsible for the modified trait(s), including a description of gene combinations in the GMO(s) (if any)	
8.3	Details of the origin(s) of the DNA to be inserted	
8.4	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	
8.5	Details of the genetic modification(s) that have been or will be made, including details of the steps involved in its construction	
8.6	Details of the stability of the genotype(s) of the GMO(s), including a statement on whether it has a potentially unstable genotype	
8.7	Details of the extent to which the genetic modification(s) has been characterised (that is, the DNA sequenced, and the potential gene products understood)	
8.8	Details of the location of the inserted DNA and the number of copies that will be present in the final construct	
8.9	Is the site of integration of the inserted DNA, within the host genome, known?	
8.10	Details of the markers or sequences that will enable the GMO(s) to be identified in the laboratory and under field conditions	
8.11	Details of the type of vector 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	
8.12	Details of whether the vector has the ability to transfer to other hosts and, if so, details of the host range	
8.13	Details of whether the recombinant vector will be present in the final construct and if not, how it will be removed	
8.14	If no vector will be involved, details of how the DNA will be introduced and how many copies of the gene will be inserted	
8.15	Details of secondary genetic effects that may be anticipated	
8.16	Details of the intrinsic genetic features, if any, of the GMO(s) that will regulate survival in the environment, including a statement on how stable those features are	
8.17	Details of the genetic changes, if any, that will be included in the GMO(s) to limit or eliminate any capacity to reproduce or transfer genes to other organisms	

Part 9: Risk assessment information – the parent organism(s)

Information		Attachment Number
9.1	Details of the common name of the parent organism(s)	
9.2	Details of the scientific name of the parent organism(s). If a GMO(s) is the result of a crossing event between more than one species, please include relevant information	
9.3	Details of the strain(s), cultivar(s) etc to be released. If a GMO(s) is the result of a crossing event between more than one strain, cultivar etc, please include all relevant information	
9.4	Details of whether the parent organism(s) has an extended history of safe use in agriculture or other industries	
9.5	Details of whether the parent organism(s) is capable of causing disease or other ill-health in people, plants or animals and, if so, the possible effects	
9.6	Details of the natural habitat of the parent organism(s), and its range	
9.7	Details of the location where the parent organism(s) was originally isolated for the purpose of the proposed dealing(s)	
9.8	Details of the distribution of the parent organism(s), and closely related organism(s), in Australia and in particular its distribution at or near the site of proposed release, including details if the parent organism(s) is exotic to Australia	
9.9	Details of any known predators, parasites, pests or diseases of the parent organism(s) in Australia	

Part 10: Risk assessment information – interaction between the GMO(s) and the environment

Information		Attachment Number
10.1	Details on whether the proposed release of the GMO(s) could prejudice any beneficial function of the parent organism(s) in the environment	
10.2	On the basis of contained experiments, details of: (i) the survival times of the GMO(s) in habitats relevant to the release; and (ii) the growth rate (or generation time) of the parent organism(s) and GMO(s) 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	
10.3	Details of the capability of the GMO(s) to disperse from the release area(s), and, if any, the dispersal mechanism	
10.4	Is the GMO(s) likely to be able to establish in the environment outside the release site(s)? If so please provide details	
10.5	Is the GMO(s) able to form long-term survival structures, such as spores? If so please provide details	
10.6	Details of whether the inserted genetic trait(s) will be able to be transferred to other organism(s) found at the release site and surrounding environment and, if so: (i) the organism(s) the trait(s) 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 organism(s) are likely to have over members of the species that do not contain the transgene(s); and (b) environmental risks posed by such an advantage	
10.7	Details of whether interactions between pathogens and the transgene(s) are possible (for example, gene silencing) and, if so: (i) the incidence and distribution of relevant pathogens; and (ii) possible effects of interaction	

Part 11: Risk assessment information – risks GMO(s) may pose to the health and safety of people

Information		Attachment Number
11.1	Details of any allergens or toxins that may be expressed by the proposed GMO(s) that are not found in the parent organism(s)	
11.2	Details of any pathogenic properties in the GMO(s) that are not found in the parent organism(s)	
11.3	Details of any occupational health and safety risks to personnel dealing with the GMO(s) and safety risks to the wider community	

Part 12: Risk management information

Information		Attachment Number
12.1	***Details of measures proposed for restricting the dissemination or persistence of the GMO(s), or its genetic material, in the environment, including details of proposed measures for disposing of the GMO(s) when the release is complete and any waste deriving from the GMO(s)***	
12.2	***Details of measures proposed for monitoring the release including monitoring for:*** ***(i) the survival or presence of the GMO(s), or transferred genetic material, beyond the proposed release site(s), 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(s) to other species; and*** ***(iv) any other hazards or deleterious effects*** ***the survival or presence of the GMO(s) after the release is completed***	
12.3	Details of the methods that will be used to minimise the effects of any transfer of the modified genetic trait(s) to other organisms	
12.4	Details of the specific experimental methods proposed for detecting the presence of the GMO(s), or transferred genetic material, in the recipient organism(s)	
12.5	Details of proposed release site supervision procedures and, if necessary, any relevant safety procedures designed to protect staff, including a description of procedures for on-site supervision of the release if the release site(s) is located at some distance from the location of the applicant	
12.6	Details of measures proposed for: (i) informing persons covered by the licence of any licence conditions; and (ii) informing the public about the proposed dealing(s)	
12.7	Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the Regulator	
12.8	Details of any contingency measures that will be in place to rectify any unintended consequence if an adverse effect becomes evident during the course of the release(s)	

Part 13: Information about current and previous assessments or approvals

Information		Attachment Number
13.1	Details of any related current application under consideration by a Commonwealth, State or overseas government authority or regulator	
13.2	Details of results of any applications made for approval or use of the GMO(s), or any derived GM products, by any other regulator in Australia or overseas, including information about whether the application was successful or unsuccessful and details of conditions (if any) attached to the approval	
13.3	Details of any previous applications (whether successful or unsuccessful) under the Act, or to the Genetic Manipulation Advisory Committee, for a dealing with the GMO(s), or of a notification of a dealing under the Act, from which the work in the present application has developed	
13.4	If the GMO(s) has been previously released in Australia or overseas, details of any adverse consequences of the release, including identifying references and reports of assessments	
13.5	A list of Commonwealth and State government authorities that have been consulted about the proposed dealings with the GMO(s)	
13.6	For an imported GMO(s) – 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)	

Part 14: Additional Information - GM plant(s)

This part has been removed due to the development of specific forms for GM plants.

Part 15: Additional information – GM micro-organism(s) not living in or on animals and not a live vaccine

Information about GMO(s) associated with plants		**Attachment Number**
15.1	Details of any partner species of plant, including information about the specificity of the interaction and the range of plant species with which the parent organism(s) can interact	
15.2	Details of the effects of the GMO(s) on the partner plant species, and details of how it will be monitored	
15.3	Details of any secondary effects that the GMO(s) might have on the partner plant species	
15.4	Details of whether the modification(s) is likely to cause any change to the range of host plant species susceptible to infection by the organism(s)	
15.5	Details of the effect, if any, of the GMO(s) on the distribution and abundance of host plant species or other species with which the GMO(s) can interact	
15.6	Details of the effect the GMO(s) might have on insects, birds, animals or humans that may eat the plant	
Information if the GMO(s) is associated with plant species that are food crops		
15.7	Details of whether the GMO(s) could affect the suitability of the resultant produce for consumption by animals or human beings and, if so, the effect	
Information about the impact of the GMO(s) on soil and water		
15.8	Details of the expected effects of the GMO(s) on local soil chemistry (for example, pH, mineral leaching and nutrient levels)	
15.9	Details of the possible effects of the GMO(s) on local water quality	
15.10	Details of the effects the GMO(s) 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(s)	
Information about any interactions between GMO(s) and closely related micro-organisms		**Attachment Number**
15.11	Details of any known interaction between the GMO(s) and closely related micro-organisms in any partner plant (if applicable) and in the environment of the release site(s)	
Information about known genetic exchange between parent organism(s) and plant pathogens		
15.12	Details of any known exchange of genetic material between the parent organism(s) and plant pathogens	
Other information		
15.13	Information about the expected survival and dispersal of the GMO(s), including dispersal in natural waters, soil and on other natural surfaces	
15.14	Details of whether the GMO(s) will be resistant to desiccation	
15.15	A list of sterilising and anti-microbial agents (if any) that are expected to be active against the GMO(s)	

15.16	Details of whether the GMO(s) will be susceptible to ultraviolet or ionising radiation	

Part 16: Additional information – GM micro-organisms that live in or on animals

You must only respond to this Part if you are proposing to deal with a **GMO(s) that is (are) a micro-organism(s) that live(s) in or on animals** (for example, gut biota living in larger hosts and bacteria applied externally to an animal to prevent foot rot).

Information about the impact of the GMO(s) on the host		**Attachment Number**
16.1	Identification of the animal host species	
16.2	Details of any new capacity the GMO(s) will provide for the host species (for example, ability to degrade plant or pasture toxins)	
16.3	Details of whether the competitive advantage, ecological fitness, biology or distribution, of the host will be altered, and relevant data (if any) on the subject	
16.4	Details of any secondary effects expected to result from the introduction of the GMO(s) 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)	
Information about the impact of the GMO(s) on the environment (particularly the impact on other animals, plants, soil and water)		
16.5	Any evidence that the GMO(s) might be capable of establishing in, or on, other animals, including feral animals	
16.6	Any evidence of other likely effects (including secondary effects) on other plants or animals in the agricultural and natural environments	
16.7	If the proposed GMO(s) will establish in an animal, information about whether the GMO(s) will be excreted or otherwise leave the animal and, if so, the time period that it is expected the GMO(s) can survive outside the animal	
16.8	Details of the possible effects of the GMO(s) on local water quality	
Other information		
16.9	Details about whether the GMO(s) will be resistant to desiccation	
16.10	A list of sterilising and anti-microbial agents (if any) that are expected to be active against the proposed GMO(s)	
16.11	Details of whether the proposed GMO(s) will be susceptible to ultraviolet or ionising radiation	

Part 17: Additional information – live GM vaccine for use in animals or humans

You must only respond to this Part if you are proposing to deal with a **GMO that is a live vaccine for use in animals or humans.**

Information about the purpose of the vaccine		**Attachment Number**
17.1	Identification of the disease to be treated, or prevented, by use of the vaccine	
17.2	Identification of the host species on which the vaccine is to be used	
17.3	Details of the host range of the parent organism from which the vaccine is constructed	
17.4	Details of the level, and duration, of immunity produced in the host species after administration of the vaccine	
Information about the vaccine		
17.5	Details of the potential for the generic material of the vaccine GMO to become incorporated in whole, or in part, into the genome of any cells of the vaccinated host	
17.6	Details of the period over which the vaccine GMO will be detectable in a test animal/person, or its excretions or secretions	
17.7	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	
17.8	Details of any deleterious effects the vaccine GMO may have on a pregnant animal/person	
17.9	Details on whether the vaccine GMO has a teratogenic effect on a foetus at any stage of gestation	
17.10	Details 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	
17.11	Details on whether the vaccine GMO is resistant to desiccation	
17.12	A list of sterilising and anti-microbial agents (if any) that are active against the GMO	
17.13	Details on whether the vaccine GMO is susceptible to ultraviolet or ionising radiation	

Information about the effect of the GMO on the environment		Attachment Number
17.14	Details of: (i) the potential for the vaccine GMO to spread from vaccinated to unvaccinated animals or people (of the same or other species including human beings); and (ii) if the potential exists, the likely mechanism and frequency of such spread	
17.15	Details of whether the susceptibility of the host to the vaccine GMO 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	
17.16	Details of proposed methods for disposing of waste containing the vaccine GMO	
17.17	Details of the intended fate of vaccinated animals at the end of the trial	
17.18	Information about whether the live vaccine GMO will be carried by an animal or person at the end of the trial and, if so: (i) the potential for dissemination of the live GMO vaccine through the person or 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 GMO to cross the placenta of a pregnant animal/person	

Part 18: Additional information – GM vertebrate animal

You must only respond to this Part if you are proposing to deal with a **GMO that is a vertebrate animal (other than aquatic organisms)**.

Information about the effects of the GMO(s) on the environment		**Attachment Number**
18.1	Information about the likelihood of any unintended effect on other animals resulting from the release of the GMO	
18.2	Information about any intended gains that are directly linked to changes in other characteristics of the subject species	
Information about feral populations of subject species, if any, that exist in Australia or that may be established		
18.3	Details of: (i) the likelihood of the introduced trait(s) 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	
18.4	Details of any agricultural, environmental or disease-control problems caused by feral populations of the subject species	
18.5	Details of any experimental work that has been done on expression of the novel genetic material in feral animals (such as cross-breeding of GMO(s) with captive feral animals), and the results of such work	
18.6	Details of the likelihood of the novel genetic material entering the feral gene pool (for example, by interbreeding with modified farm animals)	
18.7	Details 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	
Information about the capacity of the GMO(s) to interbreed		
18.8	Details of the capacity of the GMO(s) to interbreed with any species native to, or currently present in, Australia	
Information about requirements for optimal expression of the introduced trait		
18.9	Details of the management procedures and environmental factors, if any, that would be required for optimal expression of the introduced trait(s)	

Information about future dealings with the GMO(s)		Attachment Number
18.10	Details of whether an animal in the experiment is intended to be allowed to breed and, if not, whether breeding is planned in the future	
18.11	Details of whether the proposed arrangements for handling any offspring are the same as those for the experimental animal(s), and, if not, the proposed different arrangements	
18.12	Has the proposed work been reviewed by the Institutional Animal Ethics Committee? Please provide details	
18.13	Does the proposed work meet the requirements of relevant State animal welfare legislation? Please provide details	

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*, which requires review by an Institutional Animal Ethics Committee and by the relevant Authority administering State animal welfare legislation.

Part 19: Additional information – GM aquatic organism

You must only respond to this Part if you are proposing to deal with a **GMO that is an aquatic organism**, for example fish, crustaceans and molluscs.

Information about the impact of the GMO(s) on the environment		**Attachment Number**
19.1	Details of whether the GMO(s) could produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites, pests or predators and, if so, the likely effect	
19.2	Details of any unintended effects that may result from the release	
19.3	Details of 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)	
19.4	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	
Information about any impact on populations		
19.5	Information about whether 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 existing populations cause other organisms or the environment	
19.6	Information about the potential for the modified trait(s) to enhance the ability of the species to establish populations in aquatic habitats	
19.7	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 GMO(s) with wild or farmed stocks)	
19.8	Details of the likelihood of the modified genetic material entering the gene pool of established populations	
19.9	Information about any impact the entry of the modified genetic material into the gene pool of an 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	
19.10	Information about mechanisms intended to be used to prevent dispersal of the GMO(s) in the environment	
Information about future dealings with the GMO(s)		
19.11	Details of whether an organism in the experiment is intended to be allowed to breed and, if not, whether breeding is planned in the future	
19.12	Details of whether the proposed arrangements for handling any offspring are the same as those for the experimental organisms and, if not, the proposed different arrangements	

Part 20: Additional information – GM invertebrate animal

You must only respond to this Part if you are proposing to deal with a **GMO that is an invertebrate animal other than aquatic invertebrates.**

Information about the GMO(s)		**Attachment Number**
20.1	Information about the effect the GMO(s) might have on the food chain	
20.2	Information about the potential for the GMO(s) to produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites or predators	
20.3	Information about other unintended effects that may result from the release	
20.4	Details of whether the GMO(s) will be fertile and, if not, whether it is intended to use fertile organisms in later releases	
20.5	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	
20.6	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	
20.7	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	
20.8	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)	
20.9	Information about the effect, on the distribution and abundance of populations of the organism, of the entry of the novel genetic material into the gene pool of those populations	
20.10	Details of the mechanisms proposed to be used to prevent dispersal of the GMO(s) in the environment	

Part 21: Additional information – GMO(s) for biological control

You must only respond to this Part if you are proposing to deal with a **GMO(s) that is (are) to be used for biological control.**

Information about the expected interaction between the GMO(s) and the species targeted for biological control		**Attachment Number**
21.1	The name of the species targeted for biological control	
21.2	Details of any direct effects the parent organism(s) has on the target species	
21.3	Details of any direct effects the GMO(s) is expected to have on the target species	
21.4	Details of how the GMO(s) is intended to be transferred from one target organism to another, and what factors affect the transferability	
21.5	Details of the genetic response(s) that may be invoked in populations of the target organism as a result of the use of the GMO(s) (for example, increased resistance to the modified organism(s)), and the expected evidence for the response	
Information on the possible effects of the GMO(s) on non-target organisms		
21.6	Details of the host range of the GMO(s), and of any difference from the host range of the parent organism(s)	
21.7	A list of the non-target organisms that have been tested for susceptibility to the GMO(s), and the rationale for the choice of species tested	
21.8	If the modified trait(s) can be transmitted to other organisms that are likely to be in the environment of the release site, details of any effects those other organisms are likely to have on non-target species	
Information on other possible effects of the GMO(s) on the environment		
21.9	Details of the secondary effects that can be envisaged on competitors, predators, prey or parasites of the target species	
21.10	Details of the consequence of the removal, or reduction, of the target species on the management of agriculturally significant plants or farm animals	
21.11	Details of any predicted change in the ecosystem resulting from a reduction in the populations of the target organism(s)	

Part 22: Additional information – GMO(s) for bioremediation

You must only respond to this Part if you are proposing to deal with a **GMO(s) that is (are) to be used for bioremediation.**

Information about the expected interaction between the GMO(s) and the target substrate for bioremediation		**Attachment Number**
22.1	Identification of the target substrate(s) for bioremediation	
22.2	Details of the effect the parent organism(s) has on the target substrate(s)	
22.3	Details of the effect the GMO(s) is expected to have on the target substrate(s)	
22.4	A list of the substrates other than the target substrate(s) that can be metabolised by the GMO(s) and that cannot be metabolised by the parent organism(s)	
Information about the GMO(s) and its impact on the environment		
22.5	Details of whether the GMO(s) will be self-sufficient if added to the contaminated site(s) or whether additional measures may be required (for example, provision of supplementary nutrients and growth factors, or other environmental modifications)	
22.6	Details of effects the GMO(s) might have on water, air or soil quality	
22.7	Details of the effects the GMO(s) might have on organisms that ingest it	
22.8	Details of whether the GMO(s) will be dispersed from the site(s) of application and, if so, the proposed mechanisms involved and the likely consequences	

Part 23: Additional information – GMO(s) used as food for human or vertebrate animal consumption

You must only respond to this Part if you are proposing to deal with a **GMO(s) that is (are) intended to be developed for use as a food for consumption by human or animals.**

Information		**Attachment Number**
23.1	Details of: (i) whether the parent organism(s) and/or the donor organism(s) 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 to the parent or donor organism before consumption, and if processing will be different for the GMO(s)	
23.2	Details of any products of the GMO(s) that are expected to concentrate in the food chain to levels which may become toxic	
23.3	Details of any expected changes to the nutritional quality of such food as a result of the genetic modification(s)	
23.4	Details of whether the GMO(s) is a major component of such food as consumed, or a minor component (for example, yeast cells in beer)	

Note: Food that contains GMO(s) or GM products is also subject to regulation by Food Standards Australia New Zealand prior to human consumption (see assessment requirements under the *Australia New Zealand Food Authority Act 1991*).