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

Application for a licence

for dealings involving intentional release (DIR) of genetically modified (GM) plants into the environment under limited and controlled conditions

Title of the application:	Limited and controlled release of
	Enter plant species
	genetically modified for
	Enter trait(s)
Applicant organisation name:	Enter name
Accreditation number: (If the organisation is accredited by the Gene Technology Regulator)	Enter number

Are you proposing dealings that involve the limited and controlled release of a GM plant into the environment (according to section 50A of the Act)? Please see Information for Applicants section.

☐Yes ☐No If No, this is not the correct application form.

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

☐Yes ☐No

If any information provided is covered by a previous CCI application(s) or declaration(s), please provide

the relevant CCI application number(s): Enter numbers

and the organisation name(s): Enter name

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 a written application to advise you in selecting the appropriate application form and discuss information requirements. **This is particularly important if the parent plant is not present in the Australian environment.** Additionally, we welcome comments to improve this form. You can call (1800 181 030) or email.

What is this application form for?

This application form is for dealings (activities) involving **limited and controlled release of GM plants** into the environment.

To qualify as a limited and controlled release application, section 50A of the *Gene Technology Act 2000* (the Act) requires that:

- the principle purpose of the application for a licence is to enable the licence holder, and persons covered by the licence, to conduct experiments; and
- the application proposes, in relation to any genetically modified organism (GMO) in respect of which dealings are proposed to be authorised:
    - controls to restrict the dissemination or persistence of the GMO and its genetic material in the environment; and
    - limits on the proposed release of the GMO; and
- the Regulator is satisfied that the controls and limits are of such a kind that it is appropriate for the Regulator not to seek the advice referred to in subsection 50(3) of the Act.

What if your application does not meet all the above requirements?

If your application involves intentional release of a GMO other than a plant or if it does not meet the above requirements for a limited and controlled release, please use the general application form for dealings involving intentional release of a GMO into the environment or the form for commercial DIRs of GM plants, as appropriate.

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)* form. Please submit it together with this DIR licence application form.

Further explanatory material with respect to the information requirements associated with an *Application for declaration that specified information is CCI* is provided on the 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 dealings (activities). The Regulator's decision whether or not to issue a licence is based upon the RARMP.

Information in this application 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 limited and controlled release 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. We recommend you read through all the questions, including the guidance text, and also the separate document containing example answers before filling out the form. Please refer to the example answers as

indicated in this form. This will help you focus your answers on the information we need to evaluate the application.

- 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 data and references. We may ask you to provide electronic or hard copies of journal publications and unpublished information.
- Modifying text formatting in this form can be difficult. However, if you first draft the answer in a separate document and then paste it into the answer field, it should retain its formatting. Alternatively, you may provide those answers in attachments. Clearly reference any attachments you provide in response to a question, and cross-reference each attachment to the applicable question.
- 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.

If this form contains sensitive information (such as CCI) we recommend contacting our office to arrange access to the Department of Health Data Portal.

If you choose to email the information please be aware that email is 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.

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. The RARMP 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.

Please refer to the fact sheet Evaluation process - How we regulate the intentional release of GM crops and other GMOs into the environment for more information.

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 within 150 working days, or 170 working days if significant risk is identified (weekends and ACT public holidays are excluded).

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 GM plants are found outside of permitted areas
- detail a detection method specific for the GM plant and introduced genetic modification and
- report in relation to a range of 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.

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Please refer to the example answers where indicated in this form.

Personal Information

Personal information is collected by the OGTR to enable the Gene Technology Regulator to perform the functions set out the *Gene Technology Act 2000* (the Act). Personal information specified in this form is collected for the purpose of assessing applications under the Act and is handled in accordance with the Australian Privacy Principles set out in the *Privacy Act 1988*. More information can be accessed at the OGTRs Privacy and personal information web page. The OGTRs privacy policy explains how the OGTR collects, stores, uses and discloses personal information, including how a person may seek access to, or correct their personal information, and how a complaint about a breach of the APPs can be made.

Part 1: Authorised Person for the Application

The person named in this Part must be authorised to act on the applicant's behalf in relation to this application. Additionally, if a licence is issued, this person must also be authorised to act on the licence holder's behalf in all matters relating to the administration by the Regulator of the issued licence. This may include requests by the Regulator for information; matters related to compliance with licence conditions; and requests on the licence holder's behalf for variations to licence conditions. The authorised person identified here may also be the person nominated in Part 2.

Personal title, eg Ms/Mr/Dr:	Enter title
Surname:	Enter name
First name:	Enter first name
Preferred first name if different:	Enter first name
Phone number:	Enter phone number
Mobile number:	Enter mobile number
Email address:	Enter email address
Job title:	Enter job title
Organisation:	Enter organisation
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/Technical Contact

The project supervisor/technical contact(s) may be contacted by OGTR staff during assessment of the application. This person should be familiar with the application and have suitable technical knowledge and skills to answer questions about the proposed dealings.

Subject to a licence being issued, the project supervisor/technical contact(s) may also be contacted regarding monitoring compliance with the licence conditions.

Please consider whether additional persons with appropriate technical knowledge and skills could be listed for this purpose. If you wish to list more than one project supervisor/technical contact, please duplicate this page for each person.

The project supervisor/technical contact(s) will **not** be taken to be authorised to apply for licence variations, transfers and surrenders unless they are also the authorised persons for the application in Part 1.

Is the person nominated in this Part the same as the authorised person for the application in Part 1?

☐Yes ☐No

If No, please complete:

Personal title, eg 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
Email address:	Enter email address
Job title:	Enter job title
Organisation:	Enter organisation
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 Type

This information is required to establish whether your proposed dealings are subject to the *Commonwealth Gene Technology Act 2000* or to your corresponding State[1] legislation. It is advisable to check with your organisation's legal area or executive before completing this Part.

3.1 This application is being made by:

☐a natural person (proceed to Part 4)

☐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.

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

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

Part 4: Suitability of the Applicant

The Act requires the Regulator to be satisfied that an applicant is a suitable person to hold a licence before issuing a licence. Information provided in this section will assist the Regulator in making this determination.

4.1 Has the applicant been convicted of an offence against a law of the Commonwealth, a State[2] 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

[2] '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 What measures are proposed to ensure ongoing access and control of areas where dealings with GM plant(s) would occur?

If the Regulator decides to issue a licence, general licence conditions require that the licence holder be able to access and control all relevant areas, to the extent necessary to comply with relevant licence conditions, for the life of the licence,

The duration for which licence conditions apply to an area may under some circumstances extend beyond the minimum period stipulated in the licence, and therefore you would need to maintain ongoing control and access to these locations. For example, following harvest of GM plants from a field trial the licence holder may be required to monitor the area to manage spread and persistence of GM plants. Monitoring may be required for at least a minimum specified duration but may also need to continue until the Regulator 'signs-off' the area. The licence holder would need to have control of the area to comply with relevant licence conditions until otherwise notified by the Regulator.

Provide relevant information such as:

- Processes ensuring continuing access and control of relevant areas, which may include descriptions of any existing or intended contracts, agreements or other enforceable arrangements
- Details of relevant research stations or land owners and previous experience with them.

Click here to enter text.

An example answer is available.

4.9 Informing persons covered by the licence of their obligations

a. Should the Regulator decide to issue a licence, how are you proposing to inform persons covered by the licence of the conditions that apply to them?

Section 63(1) of the Act requires each licence to contain a condition that the licence holder must inform any person covered by the licence, to whom a particular condition of the licence applies, of the following:

- the particular condition, including any variations of it
- the cancellation or suspension of the licence
- the surrender of the licence.

The persons covered by the licence may include:

- persons planting, cultivating, breeding and disposing of the GM plant(s) in the field, eg researchers or contractors
- persons operating or cleaning equipment used with the GM plant(s) or GM plant materials, such as planting, harvesting or processing equipment
- persons conducting post-harvest inspections and destruction of volunteer plants
- persons importing or transporting the GM plant(s) or GM plant materials, eg truck drivers or couriers.

Enter details

An example answer is available.

b. Should the Regulator decide to issue a licence, how are you proposing to demonstrate that you have informed all persons covered by the licence as required?

For the purposes of monitoring for compliance with licence conditions, it is important for licence holders to be able to demonstrate that persons dealing with the GMO(s) have been informed of conditions of the licence relevant to them.

A general licence condition requires licence holders to obtained signed statements from people covered by the licence, stating that they have been informed of and understand relevant licence conditions, before allowing them to conduct dealings. If you do not intend to obtain signed statements from all persons dealing with the GMO(s), you must describe alternative means by which you can demonstrate that they have been suitably informed.

Enter details

An example answer is available.

Part 5: Supporting Information from the Institutional Biosafety Committee (IBC)

This part must be completed by the IBC for the applicant organisation. Parts 5 and 6 must be completed after the applicant has completed all other Parts.

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

5.1 Has the information contained in this form been checked by the IBC and have all relevant questions been answered satisfactorily?

☐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

Authorised Person for the Application as nominated in Part 1 (if different from the CEO)

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

Project Supervisor/Technical Contact (if different from the Authorised person)

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

IBC Chair

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

Part 7: Summary Information

Provide a brief summary of the proposed dealings with the GM plants intended for release.

This summary will be used to inform the public about the proposed DIR.

The summary should be brief but thorough and written in plain, non-technical English. It should include:

- a description of the GM plants proposed for release, including the:
    - plant species
    - introduced trait(s) and
- the aim of the DIR
- where the introduced genetic material originated
- proposed limits on the size and location of the release area
- proposed controls to restrict the spread and persistence of the GM plants
- any previous releases of the GM plants in Australia or overseas and whether the release resulted in harm to human health and safety or the environment
- any assessments (both pending or finalised) by other Australian or overseas regulators.

Enter summary.

An example answer is available.

Part 8: Parent Plant(s)

Information about the parent plant forms a baseline against which the GM plant is assessed to determine if the modification(s) introduced by gene technology increases the level of risk or introduces additional risks compared to the parent plant.

8.1 What is the common name of the parent plant(s)?

Include all common names that are widely used in Australia and elsewhere.

Enter answer.

An example answer is available.

8.2 What is the scientific name of the parent plant(s)? If the GM plant(s) is the result of crossing between more than one species, please specify both parents.

Include both genus and species names along with scientific names previously used in the scientific literature.

Enter answer.

An example answer is available.

8.3 Has the OGTR prepared a biology document on the parent species?

Refer to the OGTR website to find out if a biology document has been prepared.

☐Yes ☐No

If No, please complete the all sections in the remainder of the application.

If Yes, please read the biology document. Provide any new information or information relevant for the application about the parent species which is not present in the biology document (including citations) in the field below (or in an attachment). Complete the remainder of the application form, except Part 14.

Enter answer.

Part 9: Description of the GM Plant(s) and Details of the Genetic Modification

This part includes information on:

- the method of gene technology used to generate the GM plants
- details of the introduced genetic modification (alteration, insertion &/or deletion of DNA) present in the GM plants
- how to specifically identify the GM plants and
- the properties of the GM plants resulting from the introduced genetic modification.

This information can assist in risk assessment and determining appropriate control measures to manage risk.

Provide supporting evidence, including available data, published literature, and/or other regulatory assessments.

Note that this Part focuses on intended (Parts 9.1 to 9.5) as well as any unintended phenotypic changes (Part 9.6). The effects of phenotypic changes on spread and persistence of the GM plants and potential for harm to people or the environment are considered in Parts 12 and 13, respectively.

9.1 What GM plants are proposed for release?

If you are proposing a variety of GM plants with different genetic modifications for release, then categorise them and refer to those categories throughout the remainder of the application.

For each category of GM plants, indicate the maximum number of lines proposed for release (whereby a line encompasses all progeny from a single transformation event). For the GM plants in each category briefly describe which of their trait(s) is different compared to the parent organism and what modifications were introduced. Include selective markers in your description, if used.

Enter answer.

An example answer is available.

9.2 What genetic material was/will be introduced, deleted or modified compared to the parent plant(s)?

Provide a table containing the details of any nucleic acids introduced into the parent species for stable integration.

The table should provide details of the components to adequately identify any introduced genetic material. Genetic material includes the gene(s) or partial gene sequences (eg for RNAi silencing constructs) as well as the associated regulatory elements (eg promoters, targeting sequences, terminators, introns) and vector sequences that have been or will be introduced into the parent plant.

For synthetic genes or gene silencing constructs, provide information on the gene(s) on which the introduced sequence is based, and on the source organism(s) for these sequence(s) and how the genetic material has been modified or synthesised.

For each construct that has been or will be used, list the genetic elements in the order they occur.

Include in the table:

- the name of the genetic element
- its expected or observed function in the GM plant or in plasmid, as applicable
- the source organism(s), if applicable
- the gene accession number, if available and
- the relevant citation.

Enter Answer

An example answer is available.

9.3 How would the introduced genetic material be detected in the GMOs or in a recipient organism?

Provide written detection methodology to reliably and uniquely detect the GMOs or the presence of the genetic modifications in a recipient organism, and to distinguish between categories of GMOs approved for release.
For example: provide primer sequences that will uniquely detect the genes of interest using PCR methods. Include a brief description of how these will detect only the GMOs containing the genes of interest (eg primers are located within the gene of interest and the insertion site/vector sequence, respectively) and supporting information such as PCR product sizes, gel or blot results.

If methodology is currently available, please provide it here.

Enter Answer

If methodology is not yet available, please note that should a licence be issued in relation to this application, the methodology must be provided prior to commencement of any dealings with the GMOs authorised under such a licence.

Please indicate your acknowledgement of this requirement and provide an expected date for methods to be provided to the Regulator.

Enter Answer

9.4 Are any of the source organisms for the introduced genetic material:

a. present in the Australian environment?

☐Yes ☐No

Please provide details to support your answer.

Enter answer.

An example answer is available.

b. known to be allergenic to people, or toxic or pathogenic to people or other organisms?

☐Yes ☐No

Please provide details to support your answer.

Enter answer.

An example answer is available.

9.5 What methods were used to genetically modify the parent species?

Describe the methodology used to introduce the genetic modification into the parent species, citing references as appropriate. The description should include (where applicable) the vector used to introduce the genetic modification (eg *Agrobacterium*, biolistic or particle bombardment, microinjection, or other), and how transformation events were selected. If *Agrobacterium*-mediated transformation was used, indicate which measures were used to ensure that *Agrobacterium* is not present in the GM plant. Where a single GM plant contains two or more genetic modifications, describe how the different modifications were combined.

Enter your answer

An example answer is available.

9.6 What traits of the parent species were intentionally altered by the genetic modification?

Provide details on the function/mode of action of the genetic modification and the intended phenotypic effects. Effects may be based on observation of the GM plants prior to release, eg from experiments under laboratory conditions, previous releases or overseas data. If applicable, effects may be based on the observed phenotype of other plants or plant species genetically modified with the same or similar genetic material. This information may include your research and/or other published scientific literature (provide relevant citations and unpublished reports).

Provide relevant citations and unpublished reports.

Enter answer.

An example answer is available.

9.7 What unintended changes due to the genetic modification may be predicted?

With any method of genetic modification there may be unpredictable unintended changes in the resulting GM plant, eg due to insertion of an introduced gene into another coding sequence. However, previous experience may make specific unintended changes predictable. Provide detail on the latter if you are aware of any such changes. For example, introduction of a transcription factor to enhance drought tolerance (intended change) may also provide cold tolerance (predictable unintended change). Gene silencing may silence genes other than that intended. The potential for unintended changes in phenotype may be theoretical or based on the observed phenotype of the same or other plant species genetically modified with the same or similar genetic material.

Enter answer.

An example answer is available.

Part 10: Proposed Dealings with the GM Plant(s), including Limits and Controls

The Act requires regulation of certain dealings (activities) with GMOs. Dealings with a GMO are defined in section 10 of the Act and listed in Part 10.1.

To qualify as a limited and controlled release application, section 50A of the Gene Technology Act 2000 (the Act) requires that:

- the principal purpose of the application for a licence is to enable the licence holder, and persons covered by the licence, to conduct experiments; and
- the application proposes, in relation to any GMO in respect of which dealings are proposed to be authorised:
    - controls to restrict the dissemination or persistence of the GMO and its genetic material in the environment; and
    - limits on the proposed release of the GMO; and
- the Regulator is satisfied that the controls and limits are of such a kind that it is appropriate for the Regulator not to seek the advice referred to in subsection 50(3) of the Act (ie the initial advice from agencies and experts prescribed in the legislation regarding the preparation of the RARMP, which is required for DIR applications other than limited and controlled release applications).

The information provided will be used to conduct risk analysis as described in the Regulator's *Risk Analysis Framework* when preparing a RARMP in accordance with the legislation. The proposed dealings (activities) with the GM plant(s) and any limits and controls on those activities set the context for both:

- the risk assessment (which arrives at an estimate for the level of risk for the proposal) and
- the risk management plan (the scheme for managing risks from the proposed dealings).

The risk management plan forms the basis for the licence conditions, should the Regulator decide to issue a licence (section 62 of the Act). Once a licence has been issued, the licence holder can only conduct those dealings permitted by the licence.

10.1 Details of proposed dealings (activities) with the GM plant(s)

Are you proposing to:

a. conduct experiments with the GMO(s)?

One of the criteria to qualify as a limited and controlled release is that the principal purpose of the application is to enable experiments to be conducted (section 50A(4) of the Act). The Regulator must have regard to whether the applicant proposes any or all of the following be authorised by, and done under, the licence:

- testing hypotheses
- gaining scientific or technical knowledge, and
- gaining data for regulatory purposes, or for product development or marketing.

☐Yes ☐No

If No, use the general form for dealings involving intentional release of a GMO into the environment.

If Yes, provide the aim and a brief description of the experiments you are proposing to conduct. Include details on any facilities you are proposing to use, if known.

Enter Answer

An example answer is available.

b. make, develop, produce or manufacture the GMO(s)?

This dealing incudes the initial transformation events in which the GM plants were or will be created. Usually, it takes place under a separate authorisation within a certified containment facility or overseas. Breeding and propagation of the GMO are dealings considered in Parts (10.1c) and (10.1d).

☐Yes ☐No

If Yes, provide details:

Enter answer.

c. breed the GMO(s)?

This includes the production and selection of progeny involving sexual crosses with another cultivar or strain of the same or different species. Examples include a GM plant that is crossed or backcrossed with elite germplasm or with other GM plants.

Note that if independent GM plants are intended to be crossed to produce offspring containing the genetic modifications of the independent GM parents, the resulting GM plants should be described in this application (eg Part 9). Similarly, breeding to intentionally transfer the genetic modification from the GMO to a different species should be described in this application

☐Yes ☐No

If Yes, provide details:

Enter answer.

An example answer is available.

d. propagate the GMO(s)?

This includes maintaining GM plants via asexual propagation or sexual reproduction, eg multiplication of a GM plant during seed production.

☐Yes ☐No

If Yes, provide details:

Enter answer.

An example answer is available.

e. use the GMO(s) in the course of manufacture of a thing that is not a GMO?

This includes processes which destroy the viability of GM plant materials. The resulting products may or may not contain genetic material. Examples include: ginning of cotton fibres and linters, extraction of oil from cotton or canola seeds, production of processed animal feed, and milling of wheat or barley seed to produce flour.

☐Yes ☐No

If Yes, indicate how the GMO would be used and provide further details where any of these uses would differs from the industry standard practices for this plant species:

Enter answer.

f. grow, raise or culture the GMO(s)?

☐Yes ☐No

If Yes, provide details on: whether and how the GM plants would be irrigated; the kind of propagule planted (seed or vegetative propagule); planting equipment; row spacing; weed, pest and disease management; fertiliser application and other cultivation practices; harvesting equipment; whether the GM plants would be replanted on the same area of land in subsequent growing seasons; and if and which rotation crops are proposed:

Enter answer.

An example answer is available.

g. import the GMO(s)?

☐Yes ☐No

If Yes, provide a brief description of what GM plant material would be imported, where it would be imported from and if a permit has been applied for and/or obtained from Department of Agriculture and Water Resources (Biosecurity).

Enter answer.

An example answer is available.

h. transport the GMO(s)?

☐Yes ☐No

Provide details on how the GM plant material would be transported in Part 10.3.

i. dispose of the GMO(s)?

☐Yes ☐No

Provide details of disposal in Part 10.3.

j. possess, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned above?

☐Yes ☐No

Provide details on how the GM plant material would be stored in Part 10.3.

10.2 Proposed limits for the DIR

Are you proposing to limit:

a. the scope of the dealings with the GMO(s)?

Scope can be considered in terms of the range of activities which are proposed to be conducted. In part this includes the dealings intended to be conducted, which is already addressed in Part 10.1. Other limitation of scope may be any limitation on activities with, or use of, the GM plant beyond those normally applying to the parent plant, eg only growing a GM plant to a particular life stage; not using the GM plant or its products for animal feed or human food; only conducting those activities needed to address a particular experimental goal, such as gathering agronomic data, after which all GM plants will be destroyed.

☐Yes ☐No

If Yes, noting that details of the scope will be provided elsewhere in the application form, briefly describe the key limitations of scope.

Enter answer.

An example answer is available.

b. the scale of the dealings with the GMO(s)?

☐Yes ☐No

If Yes, provide details on the type and number of release sites, total area for each site and the total combined area for the proposed release. Examples of the types of release sites include: a field site, areas of non-PC2 glasshouses, nursery benches or crossing facilities that may be used during the proposed release.

Enter answer.

An example answer is available.

c. the locations of the dealings with the GMO(s)?

☐Yes ☐No

If Yes, list the State(s) and LGA(s) for the proposed release and if known at time of application, the research station, street address, or GPS coordinates. Names and contact details of the land owners for the location of these trials are not required at this time. Specify all areas where the GM plants will be grown such as fields, glasshouses, nurseries and crossing facilities etc as these are considered as separate locations. Indicate if the location(s) has been, or is being, used for dealings with GM plants which were approved under an existing or previous licence.

Enter answer.

An example answer is available.

d. the facilities in which experimentation, storage or disposal of the GMOs are conducted to only certified facilities?

☐ Yes ☐ No

If No, and you propose to conduct dealings in an uncertified facility that will not be covered by an NLRD, please include the following information for each proposed facility:

- Name and address of the facility. If the facility is part of a building, please provide further details (eg building level, room number etc.)
- Purpose for which the facility would be used
- Is the facility lockable?
- Do you own the facility? If not, do you have any agreement in writing with the owner for control and access to the facility?

e. the duration of the dealings with the GMO(s)

☐Yes ☐No

If Yes, include details on the intended production cycle, such as the growing season, and total number of months or years proposed for the release. Also provide the anticipated start and end dates for the growing of the GM plants.

In considering the potential start date, note the timeframes in which the Regulator must make a decision to issue, or refuse to issue, a licence, detailed in the Information for Applicants at front of the application form.

Enter answer.

An example answer is available.

f. the persons who are to be permitted to conduct the dealings with the GMO(s)

☐Yes ☐No

If Yes, provide the roles, positions or relationship to the applicant of people who would conduct the dealings, ie the persons covered by the licence.

Note that should a licence be issued, persons covered by the licence must be sufficiently skilled to do the task they are engaged to carry out and they must be informed of the licence conditions that are applicable to them (see Part 4).

Enter answer.

An example answer is available.

10.3 Proposed controls for the DIR

Provide information on any industry standard practices used to restrict the spread and persistence of the parent plant(s) that would be relied on as control measures, as well as on proposed controls that are additional to or altered from standard practices. Provide a rationale for the effectiveness of the proposed control measures with regard to restriction of the spread and persistence of the GM plant and its genetic material.

a. Are you proposing controls to restrict gene flow via pollen dispersal from sexually reproducing GM plants while the GM plants are growing?

☐Yes ☐No

If Yes, provide details. Examples include: site selection to exclude sexually compatible plants in the vicinity; monitoring for and removal of sexually compatible species outside the release site; the use of pollen traps; isolation zones; use of sterile or low fertility GM lines, cultivars or varieties; bagging flowers; use of insect nets; preventing flowering.

Enter answer.

An example answer is available.

b. Are you proposing controls to restrict the spread of seeds or asexual propagules from the site while the GM plants are growing?

☐Yes ☐No

If Yes, provide details. Examples include: criteria for site selection; cleaning equipment and clothing after use with the GM plants; distance of GM plantings from waterways; bagging of fruit; using particular seeding or harvesting methods or equipment known to minimise dispersal; or treating non-GM material at the site the same as GM material.

Enter answer.

An example answer is available.

c. Are you proposing to control access to the GM plants or site(s) by people or animals?

☐Yes ☐No

Provide details. Examples include: site selection in a remote area to restrict access by unauthorised people; fencing; locked gates; and animal baiting/traps. Where applicable, explain why controlling access is not proposed.

Enter answer.

An example answer is available.

d. Are you proposing controls to restrict persistence (and spread) of the GM plant(s) at the site post-harvest?

☐Yes ☐No

If Yes, provide details. Examples include: monitoring areas for a specified time period and destruction of GM plants; tilling and watering to encourage germination of any seed bank; seed reduction measures; harvest procedures to minimise seed bank build-up.

Enter answer.

An example answer is available.

e. Are you proposing controls to restrict dispersal of the GMOs during transport?

☐Yes ☐No

If Yes, provide detail. Describe who would transport the GM plants or GM plant material; how it would be contained during transport and how it would be transported, including the use of specific transport equipment or commercial courier services. Refer to the Regulator's guidelines for transport, storage and disposal of GMOs where appropriate and detail how you would implement those guidelines.

Enter answer.

An example answer is available.

f. Are you proposing controls to restrict dispersal of the GMOs during storage?

☐Yes ☐No

If Yes, provide detail. Refer to the Regulator's guidelines for transport, storage and disposal of GMOs where appropriate and detail how you would implement those guidelines. Other relevant controls may include storage of the GMO in a locked facility and cleaning and monitoring of storage areas.

Enter answer.

An example answer is available.

g. Are you proposing controls to restrict dispersal of the GMOs during disposal?

☐Yes ☐No

If Yes, provide detail. Refer to the Regulator's guidelines for transport, storage and disposal of GMOs where appropriate and detail how you would implement those guidelines. Include what destruction

methods would be used and relevant controls such as monitoring of destruction areas, using specific methods or equipment for destruction or cleaning of areas used outside of the trial site(s).

Enter answer.

An example answer is available.

10.4 Are you required to obtain approval for the use of the GM plant(s), or products from the GM plant(s), from other Australian regulatory schemes during the course of the proposed limited and controlled release?

Some uses of GMOs or GM products are covered by legislation administered by other regulatory agencies such as:

- Food Standards Australia and New Zealand (FSANZ) – regulation of food products, labelling GM foods
- Australian Pesticides and Veterinary Medicines Authority (APVMA) – regulation of agricultural chemicals used on or produced by crops and veterinary therapeutic products
- Therapeutic Goods Administration (TGA) – regulation of human therapeutic products
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS) – regulation of chemical safety
- Department of Agriculture and Water Resources (Biosecurity) – regulation of importation of animals, plants and biological products (see also Part 10.1.g)

Information provided here assists co-ordination with these other regulatory agencies.

You will be asked to provide details about current assessments and previous approvals of the GM plants proposed for release in Part 11 of this application.

a. Is use in or as a commercially available human food intended?

☐Yes ☐No

If Yes, briefly describe how the GMO will be used for human food and if this use differs from standard use of the species for human food.

Enter answer.

b. Is use as an agricultural chemical intended?

☐Yes ☐No

If Yes, briefly describe how the GMO will be used as an agricultural chemical, eg the GM plant may produce a compound which is toxic to specific insect pests.

Enter answer.

An example answer is available.

c. Would agricultural chemicals be used on the GM plant(s)?

☐Yes ☐No

If Yes, briefly describe which chemicals (eg herbicide, insecticides, fungicide) would be used and if the usage differs from the industry standard practices. Note that question 11.2 asks about the regulatory approval for chemical use on the GM plant.

Enter answer.

An example answer is available.

d. Is use in or as a veterinary medicine intended?

☐Yes ☐No

If Yes, briefly describe how the GMO would be used in or as a veterinary medicine.

Enter answer.

e. Is use in human therapeutics intended?

☐Yes ☐No

If Yes, briefly describe how the GMO would be used in or as a human therapeutic.

Enter answer.

f. Is use in or as an industrial chemical intended?

☐Yes ☐No

If Yes, briefly describe how the GMO would be used in or as an industrial chemical.

Enter answer.

10.5 Are you required to seek oversight by ethics committees in connection with the proposed limited and controlled release?

For example, where a GM plant or its product is intended for use in a nutritional study with people or a feeding study with animals, oversight by an appropriate committee is required.

a. Is use in a nutritional study with people intended?

Such studies are subject to oversight by a Human Research Ethics Committee which is required to review and approve the research proposals in accordance with the National Statement on Ethical Conduct in Human Research (2007 – updated 2009).

☐Yes ☐No

If Yes, describe the details of the intended study.

Enter answer.

b. Is use in a feeding study with animals intended?

An animal feeding study requires approval from an Animal Ethics Committee operating in accordance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes. Such studies must occur in accordance with the relevant legislation.

☐Yes ☐No

If Yes, describe the details of the intended study.

Enter answer.

c. Other

☐Yes ☐No

If Yes, describe the details of the intended study and the nature of the ethics committee oversight required.

Enter answer.

10.6 Will any of the proposed dealings with GM plants involve the use of nanotechnology, or inclusion or production of engineered nanomaterials?

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 (Australian Government, Department of Industry).

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**.

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

☐Yes ☐No

If Yes, provide details.

Enter answer.

Part 11: Assessments and Approvals by Regulatory Authorities

In accordance with Regulation 10(1)(a), information on current and previous assessments of the GM plant(s), both in Australia and overseas, will be taken into account in the evaluation of this application. It may also assist in risk identification or provide additional information related to impact from the history of use of the GM plant or its products, eg whether or not adverse outcomes or unintended effects have been observed.

11.1 Provide details of previous approvals for release into the Australian environment of the GM plant(s).

Include approvals by the Regulator (or the Genetic Manipulation Advisory Committee) and details of any adverse consequences resulting from the previous release(s), including identifying references and reports of assessments.

Enter answer.

An example answer is available.

11.2 Provide details of any previous, future and/or current assessments of the GM plant(s), or products derived from it, by any other regulatory authority in Australia.

Include assessments by other regulatory agencies such as FSANZ, APVMA, NICNAS, TGA and Department of Agriculture and Water Resources (Biosecurity). Also provide details of any adverse consequences associated with use of the GM plant(s) or GM products covered in these assessments, including identifying references and reports of assessments.

Enter answer.

An example answer is available.

11.3 Provide details on approvals for human food and/or animal feed use or environmental release of the same GM plant(s) in other countries.

If the GM plant(s) has been released overseas, provide details of the approvals (ie countries and type of release/approval), including when and if they are still current. Also provide details of any adverse or unintended consequences associated with the GM plant(s) or its products following their approval in other countries, including identifying references and reports of assessments.

Enter answer.

An example answer is available.

11.4 Have the GM plant(s) been refused approval, or had an approval for environmental release, or for use in human food or animal feed suspended or revoked in any country?

☐Yes ☐No

If Yes, provide details including the country, date and rationale for refusal, including identifying references and reports of assessments.

Enter answer.

Part 12: Spread and Persistence of the GM Plant(s) in the Environment

Characteristics that influence the persistence (establishment, survival and reproduction) and spread (dispersal of the plant or its genetic material) of a plant species impact on the degree of its invasiveness. The degree of invasiveness of a plant species in a particular environment gives an indication of the likelihood of it causing harm in that environment. The information required in this Part helps to establish whether plant characteristics relating to spread and persistence might be altered in the GM plant or any of its hybrids compared to the parent species.

In the preparation of the risk assessment, this information will contribute to the estimation of the exposure of people or the environment to the GM plant. In the preparation of the risk management plan, this information is used when considering the effectiveness of the limits and controls proposed in Part 10.

Potential adverse effects (ie harms) due to exposure of the GM plant to people or the environment are considered in Part 13.

The OGTR has prepared biology documents for a number of parent species. Some of these documents contain a weed risk assessment for the species which may be useful when considering the following questions.

12.1 Compared to the parent species, is the genetic modification expected to alter persistence of the GM plant at the release site?

☐Yes ☐No

Include any observed or expected alterations to the GM plant's ability to persist at the release site, such as its ability to form long-term survival structures including seed or vegetative propagules, or changes in seed dormancy, germination or time to reach reproductive maturity compared to the parent plant. Provide evidence and/or rationale for this expectation.

Enter answer.

An example answer is available.

12.2 Provide details on the likelihood of spread and persistence of the GM plant outside of the proposed release site.

Mechanisms by which the GM plants might spread outside the proposed release site(s) under both normal and extreme environmental conditions (eg floods, cyclones or bushfires), as well as the proposed limits and controls, are important in determining the likelihood of spread and persistence occurring.

a. Is the GM plant more likely to be spread outside the release site than the parent species?

☐Yes ☐No

Provide evidence or a rationale for your answer. Factors influencing likelihood of spread may include GM plants with lower seed weight than the parent or with altered seed shattering characteristics.

Enter answer.

An example answer is available.

b. Compared to the parent species, is the GM plant's ability to persist amongst existing plants expected to increase?

☐Yes ☐No

Provide evidence or a rationale for this expectation of a competitive advantage and, if applicable, indicate in what environments or under what circumstances this may occur. Include any alterations to the GM plant's ability to persist in the environment. This would include consideration of its ability to form long-term survival structures such as seed or vegetative propagules and changes in seed dormancy, seedling vigour, germination frequency, time to germinate or time to reach reproductive maturity compared to the parent species.

Enter answer.

An example answer is available.

c. Will environmental factors which naturally limit the spread and persistence of the parent species also limit the spread and persistence of the GM plant?

☐Yes ☐No

Provide evidence or a rationale for your answer.

Enter answer.

An example answer is available.

12.3 If the GM plant(s) are able to reproduce sexually, which sexually compatible plants may be present in the receiving environment?

Include the parent species, any compatible commercially approved GM plants and any other sexually compatible species in your considerations.

Enter answer.

An example answer is available.

12.4 Are any characteristics expected to be altered in the GM plant(s) compared to the parent plant that affect the efficiency of gene transfer and introgression into any sexually compatible species?

☐Yes ☐No

Characteristics that may affect the efficiency of gene transfer and introgression include the timing of flowering, flower fragrance, pollen size or shape, pollen production, pollen viability, the mechanism of pollen transfer or altered expression of genes involved in meiosis or sexual reproduction. Should a genetic modification be targeted at decreasing or abolishing the ability of the plant to reproduce sexually, include a consideration about how likely reversion would be and if any proposed controls would still be applicable. Provide the rationale for your response.

Enter answer.

An example answer is available.

12.5 If the introduced genetic modification were transferred to a different sexually compatible species (not the same species as the GMO), would the presence of the genetic modification enhance the ability of the resultant GMO to spread and persist compared to the non-GM sexually compatible species?

☐Yes ☐No

Provide evidence or a rationale for your answer.

Enter answer.

An example answer is available.

Part 13: Potential Harms of the GM Plant(s)

When preparing a RARMP the Regulator must take into account the potential of a GMO to cause harm. The GMOs in this application are GM plants. Being plants, they may cause harms, including:

- adverse effects on the health of people and/or animals
- reduction in the establishment, yield and/or quality of desired plants
- restriction in the physical movement of people, animals, vehicles, machinery and/or water
- adverse effects on environmental health, such as providing food and/or shelter to pests, pathogens and/or diseases, or adverse changes to fire regime, nutrient levels, soil salinity, soil stability or the soil water table.

In the long term, plants may also cause more complex harms such as adverse changes to biodiversity.

This section seeks to determine whether the potential of the GM plant or its offspring to cause harm would be **greater** than that of the **parent plants**, ie the non-GM parent species including any relevant commercially approved GM plants within that species.

The potential of a GM plant to cause harm is considered in the context of the limits and controls described in Part 10. Occupational health and safety requirements by other relevant regulatory authorities may also be important factors and should be included in the answers.

For each question below, provide details on the properties of the GM plant or its products that may cause harm to human health and safety or the environment due to the introduced genetic modification. The OGTR has prepared biology documents for a number of parent species which may be useful when considering the following questions.

For all 'Yes' responses provide details on:

- how people or the environment may be harmed
- the degree of harm (eg for people: acute or chronic illness, physical injury or allergy; for other organisms: displacement, toxicity or disease)
- the number of people or type of organism potentially exposed and susceptible (eg lepidoptera for Cry1 insect toxin)
- the value of potentially harmed species (eg protected/ threatened *versus* pest) and their relative abundance at the location(s) of the release
- which part of the GM plant, stage of growth or use (such as stockfeed) would cause the harm and
- whether or not the harm is reversible.

13.1 Is the GM plant expected to be more harmful to people than the parent plant?

In the context of the limits and controls, could the GM plant proposed for release or its offspring cause greater harm than the relevant comparator plants? Considerations may include:

- staff experiencing or observing adverse health effects during development of the GM plant
- genetic elements obtained from a source organism known to cause toxicity or allergenicity in people or to be pathogenic
- phenotypic changes in the GM plant that would lead to more severe physical injury to people than the non-GM parent plant
- similar GM plants causing harm to human health or safety.

☐Yes ☐No

Provide evidence and/or rationale for this expectation.

Enter answer.

An example answer is available.

13.2 Is the GM plant expected to be more harmful to organisms other than people when compared to the parent plant?

In the context of the limits and controls, could the GM plant proposed for release or its offspring cause greater harm to organisms other than people than the relevant comparator plants? This question intends to cover all organisms other than humans, including all animals, plants and microorganisms, in terrestrial or aquatic environments. Considerations may include:

- staff observing adverse effects on animals, including insects, during development of the GM plant
- genetic elements obtained from a source organism known to be toxic or pathogenic to organisms other than humans
- phenotypic changes in the GM plant that would lead to more severe physical injury to animals than the non-GM parent plant or that would smother other plants, eg changed growth habit from upright to rambling
- similar GM plants causing harm to animals or plants.

☐Yes ☐No

Provide evidence and/or rationale for this expectation.

Enter answer.

An example answer is available.

13.3 Is the phenotype of the GM plant altered such that it could harm the environment more than the parent plant?

In the context of the limits and controls, could the GM plant proposed for release or its offspring cause greater harm to the environment than the relevant comparator plants? Considerations may include:

- staff observing adverse environmental effects during development of the GM plant, eg adverse effects on soil health such as increased salinity
- genetic elements obtained from a source organism known to cause harm to the environment
- phenotypic changes in the GM plant that would lead to more severe damage to the physical environment than the parent species, eg substantial increase in height and biomass compared to the parent leading to changes in the fire regime
- similar GM plants causing environmental harm.

☐Yes ☐No

Provide evidence and/or rationale for this expectation.

Enter answer.

An example answer is available.

Part 14: Additional Information about the Parent Plant(s)

Do not complete if the OGTR has prepared a biology document. However, any new information or information relevant for the application about the parent species which is not present in the biology document must be provided (see Part 8.3).

If the parent species is not present in the Australian environment, we advise you to discuss this with OGTR staff before submitting an application.

14.1 Production and use(s) of the parent species

a. Is the parent species grown in Australia?

☐Yes ☐No

If Yes, provide details of the production methods used in the area(s) proposed for release. If a production manual is available, provide the reference.

If No, or no information is available, provide details of the information sources checked.

Enter answer.

An example answer is available.

b. Is the parent species or products derived from it used in Australia?

☐Yes ☐No

If Yes, provide details of the major uses in Australia, and briefly describe its history of use.

If No, or no information is available, provide details of the information sources checked.

Enter answer.

An example answer is available.

14.2 Distribution of the parent species in Australia

In considering the distribution of the parent species in Australia we have adopted elements of the Australian Land Use and Management (ALUM) classification system for describing various land use areas. The ALUM classification has six primary classes of land use that are distinguished in order of generally increasing levels of intervention or potential impact on the natural landscape. In this document we have followed this classification with the exception of combining the dryland and irrigated agricultural and plantation classes into one class. A description of each class is provided as background in the following questions.

a. Is the parent species present in conservation or natural environments?

Conservation or natural environments are areas that have had relatively low levels of human intervention. These areas include national or state parks, nature reserves, World Heritage sites, Ramsar wetlands, habitats for a protected species, residual native cover and areas undergoing rehabilitation.

☐Yes ☐No

If Yes, provide information on the distribution of the parent plant in these areas in Australia.

If No, or no information is available, provide details of the information sources checked.

Enter answer

An example answer is available.

b. Is the parent species present in relatively natural land use areas?

Relatively natural land use areas are areas used for primary production, with limited change to native vegetation. These areas are generally subject to relatively low levels of intervention (very limited weed control or other inputs), eg areas of natural vegetation used for grazing and native forests used for wood or other forest products.

☐Yes ☐No

If Yes, provide information on the distribution of the parent plant in these areas in Australia.

If No, or no information is available, provide details of the information sources checked.

Enter answer.

c. Is the parent species present in areas used for agricultural or plantation production (either dryland or irrigated land use)?

Relevant areas include land used for primary production based on dryland or irrigated farming systems. The range of activities in this category includes plantation forestry, pasture production, cropping and fodder production and a wide range of horticultural production.

☐Yes ☐No

If Yes, provide information on the distribution of the parent plant in these areas in Australia.

If No, or no information is available, provide details of the information sources checked.

Enter answer.

An example answer is available.

d. Is the parent species present in intensive use areas?

Intensive use areas include areas that experience high levels of interference with natural processes, generally in association with closer settlement, such as some areas used for horticulture (eg glasshouses, shadehouses), intensive animal production (eg dairy cattle, poultry), areas of manufacture or industry, residential areas, service areas (eg shops, markets, education, sportsgrounds), areas of transport and communication (eg along roadsides or railways, ports, radar stations), areas used for utilities (eg facilities that generate electricity, substations, along power lines, gas storage or treatment areas), mine sites (including tailings), and areas used for waste treatment and disposal.

☐Yes ☐No

If Yes, provide information on the distribution of the parent plant in these areas in Australia.

If No, or no information is available, provide details of the information sources checked.

Enter answer.

An example answer is available.

e. Is the parent species present in aquatic environments?

Aquatic environments include lakes, reservoirs/dams, rivers, channels/aqueducts, marshes/wetlands, estuaries, or coastal waters.

☐Yes ☐No

If Yes, provide information on the distribution of the parent plant in these areas in Australia.

Enter answer.

14.3 How does the parent species reproduce?

Include details of sexual and/or asexual reproduction such as:

- the means of reproduction, eg seed, rhizome, stolon, bulb, corm, detached stem/branch
- the time for completion of a lifecycle, eg from seed to seed
- the longevity and dormancy of propagules.

For each relevant land use identified in 14.1, indicate how many propagules may be produced per square metre.

Enter answer.

An example answer is available.

14.4 For sexually reproducing species, what are the pollen dispersal mechanisms?

Include information on the method(s) of spreading (biotic or abiotic vectors), the maximum dispersal distance and the viability of the pollen. For insect or animal vectors of pollination, include details of their range and distribution in Australia (where known).

Enter answer.

An example answer is available.

14.5 For sexually reproducing species, what sexually compatible relatives are present in Australia and what is their efficiency of hybridisation with the parent species?

Provide the scientific name and common name(s) of the sexually compatible relatives, as well as cultivated or wild members of the same species. Describe the efficiency with which hybridisation occurs under natural conditions and the fitness, survival and competitiveness of the resulting progeny, providing supporting scientific evidence where available.

Enter answer.

An example answer is available.

14.6 What harms does the parent species cause?

For the purpose of this document, invasive plants causing significant levels of one or more of the following harms are called weeds:

- adverse effects on the health of people and/or animals
- reduction in the establishment, yield and/or quality of desired plants
- restriction in the physical movement of people, animals, vehicles, machinery and/or water
- provision of food and/or shelter to pests, pathogens and/or diseases
- adverse effects on environmental health, such as providing food and/or shelter to pests, pathogens and/or diseases, or adverse changes to fire regime, nutrient levels, soil salinity, soil stability or the soil water table.

A plant species may be weedy in one or more land uses or ecosystem types. The questions to determine the weediness of the parent species have been adapted from HB 294:2006, National Post-Border Weed Risk Management Protocol (Standards Australia; Standards New Zealand).

For parent plants that are deliberately planted and grown, eg in silviculture, agriculture or horticulture, answer the questions in relation to the plant as a volunteer or otherwise outside of cultivation, not in relation to situations in which it is the desired plant.

If the answer provided to any of the following questions is ‘yes’, provide details of the harms for all the relevant land uses (agricultural or plantation production; intensively used areas; relatively natural environments; conservation or natural environments; or aquatic environments).

a. Does the parent species have an adverse effect on the health of people and/or animals?

For example, gluten in wheat can cause ill health for coeliacs (gluten intolerance), and grain dust can cause allergies in workers in a flour mill. Cotton seed contains gossypols that can be toxic to livestock if provided at high doses (eg if eaten as cotton seed meal). Additionally, toxins may be produced by organisms which normally infect or form symbiotic relationships with the parent, such as endophytes harboured in perennial ryegrass that may cause staggers in grazing animals, or fungal pathogens of plants may produce mycotoxins which affect animals or people consuming the grain from the infected plant.

☐Yes ☐No

If Yes, provide details.

If No, or no information is available, provide details of the information sources checked.

Enter answer.

An example answer is available.

b. Does the parent species cause a reduction in the establishment or yield of desired plants?

☐Yes ☐No

Describe the impact in each relevant land use, including information on which plants are valued in those areas.

Enter answer.

An example answer is available.

c. Does the parent species cause a reduction in the quality of products, diversity or services obtained from a relevant land use?

A plant may cause a loss in the supply, quality or usage of desired products, diversity or services obtained from a particular land use area. A plant may affect products by tainting of meat or milk, discolouration, tainting or otherwise reducing the quality of water, weed seed contamination of grain, seed, hay, wool, fruit or timber.

Indigenous use of native bush tucker and materials, and the quality of products of sustainable harvesting, should be considered here if applicable. Adverse impacts on fishing and hunting by all members of the community are also considered here.

In native vegetation, the decline of native plant species diversity and abundance are the main concerns (with flow on effects to animal diversity). This affects ecosystem structure and function and eventually conservation significance, recreational and tourism values. Plants may threaten biodiversity by harming threatened plant and animal species or communities.

In residential areas the plant may cause damage to physical infrastructure such as buildings, roads, fences and footpaths or it may reduce visibility, which may lead to harm to human health.

☐Yes ☐No

If Yes, describe.

If No, or no information is available, provide details of the sources checked.

Enter answer.

An example answer is available.

d. Does the parent species cause a restriction in the physical movement of people, animals, vehicles, machinery and/or water?

Plants may restrict movement by being tall, thorny, tangled and / or dense. Examples of plants restricting movement by creating a physical barrier include:

- Blocking or slowing access of cars, bikes, quad bikes, farm / forestry machinery or other machinery
- Impeding movement of people on foot
- Interfering with boat access or manoeuvrability
- Blocking or slowing water flow
- Preventing livestock access to pasture or water
- Preventing animal access to nesting sites.

☐Yes ☐No

If Yes, describe.

If No, or no information is available, provide details of the sources checked.

Enter answer.

An example answer is available.

e. Does the parent species provide food or shelter to pests, pathogens and/or diseases?

☐Yes ☐No

If yes, describe.

If No, or no information is available, provide details of the sources checked.

Enter answer.

An example answer is available.

f. Does the parent species cause adverse effects on environmental health?

Adverse effects on environmental health include adverse changes to nutrient levels, fire regime, soil salinity, soil stability or soil water table.

☐Yes ☐No

If yes, describe.

If No, or no information is available, provide details of the sources checked.

Enter answer.

14.7 What is the ability of the parent species to establish in competition amongst existing plants in each relevant land use?

Indicate which statement(s) about the parent species' ability to establish is most applicable. Select more than one statement if the plant's ability to establish is different for the relevant land uses.

☐The plant readily establishes within dense vegetation, or amongst thick infestations of other weeds, ie it has a very high ability to establish.

☐The plant readily establishes within more open vegetation, or amongst average infestations of other weeds, ie it has a high ability to establish.

☐The plant mainly establishes when there has been moderate disturbance to existing vegetation, which substantially reduces competition, ie it has a medium ability to establish. Moderate disturbance could include intensive grazing, mowing, raking, clearing of trees, brief floods or summer droughts.

☐The plant mainly needs bare ground to establish, including removal of stubble/leaf litter, ie it has a low ability to establish. This will occur after major disturbances such as cultivation, overgrazing, hot fires, grading, long-term floods or long droughts.

☐The plant's ability to establish is unknown.

Provide a rationale or evidence for the indicated ability to establish in each relevant land use.

Enter answer.

An example answer is available.

14.8 What factors normally contribute to the long distance (>100 metre) spread of the parent species in the environment?

Factors that normally contribute to the dispersal of the parent plant are likely to apply to the GM plant and may need to be managed in order to control the release. Consider all forms of dispersal, including seed, roots, corms, rhizomes, stolons, stems etc.

a. Is the parent species spread by flying animals?

Indicate which statement about the parent species' spread via flying animals is most applicable.

☐Flying animals, such as birds or bats, are well known to defecate, regurgitate or discard viable plant material or to spread it on fur, feathers, skin or feet, eg due to stickiness, small size or the presence of hooks or burrs.

☐Occasionally, flying animals spread viable plant material.

☐Flying animals do not disperse viable plant material or the species is avoided.

☐The ability for the parent plant to be spread by flying animals is unknown.

Provide a rationale or evidence for your answer. If flying animals are known to spread the parent species, provide their common and scientific names.

Enter answer.

An example answer is available.

b. Is the parent species spread by wild animals other than flying animals?

Indicate which statement about the parent species' spread is most applicable.

☐Wild animals other than flying animals are well known to defecate or discard viable plant material or spread it on hairs, skin or feet, eg due to stickiness, small size or the presence of hooks or burrs.

☐Occasionally, wild animals other than flying animals spread viable plant material.

☐Wild animals other than flying animals do not disperse viable plant material or avoid the species.

☐The ability for the parent plant to be spread by wild animals other than flying animals is unknown.

Provide a rationale or evidence for your answer. If wild animals other than birds are known to spread the parent plant, provide their common and scientific names.

Enter answer.

An example answer is available.

c. Is the parent species spread over long distances via water?

Indicate which statement about the parent species' spread via water is most applicable.

☐Viable plant material is known to be spread by water, eg the propagules float or the species is located in or near to moving water or in areas that flood frequently.

☐Occasionally, viable plant material is spread by water.

☐The species is not spread by water.

☐The ability for the parent plant to be spread over long distances via water is unknown.

Provide a rationale or evidence for your answer.

Enter answer.

An example answer is available.

d. Is the parent species spread over long distances via wind?

Indicate which statement about the parent species' spread via wind is most applicable.

☐Viable plant material is known to be spread over large distances by wind, eg the species grows tall and produces small and light seeds or the species produces light seeds with wings, plumes or hairs.

☐Occasionally, viable plant material is spread by wind.

☐The species is not spread by wind.

☐The ability for the parent plant to be spread long distances via wind is unknown.

Provide a rationale or evidence for your answer.

Enter answer.

An example answer is available.

e. Is the parent species deliberately spread by people?

Indicate which statement(s) about the parent species' deliberate spread by people is most applicable. Note that this may differ for different relevant land uses, eg a species may be used as a pasture species and deliberately spread in a pasture land use; it may not be deliberately spread in a nature conservation area. Select more than one statement if there are differences between the relevant land uses.

☐Viable plant material is or has been deliberately spread by people, eg it is used in agriculture, silviculture, horticulture, for medicinal, aquatic, turf, amenity, windbreak, shelter or soil protection purposes.

☐Viable plant material is occasionally spread deliberately by people.

☐The species is not known to be spread deliberately by people.

☐The ability for the parent plant to be spread deliberately by people is unknown.

Provide a rationale or evidence for your answer.

Enter answer.

An example answer is available.

f. Is the parent species accidentally spread by people?

Indicate which statement(s) about the parent species' accidental spread by people is most applicable. Note that this may differ for different relevant land uses, eg it may not be accidentally spread in a nature conservation area as these areas may not be accessed by humans as much as other land use areas. Select more than one statement if there are differences between relevant land uses.

☐Viable plant material is known to be accidentally spread by people, eg the species grows in heavily trafficked areas, such that transport by footwear, clothing or vehicles, including farm machinery and boats, may occur or the species is often dragged by farm machinery or propagules have hooks, barbs or sticky substances to attach to objects or the species produces small propagules which can lodge in cracks in footwear, clothing or vehicles.

☐Occasionally, viable plant material is spread accidentally by people.

☐The species is not known to have been accidently spread by people.

☐The ability for the parent plant to be spread accidentally by people is unknown.

Provide a rational or evidence for your answer.

Enter answer.

An example answer is available.

g. Is the parent species spread via domestic or farm animals?

Indicate which statement(s) about the parent species' spread via domestic/farm animals is most applicable. Select more than one statement if there is a difference between the relevant land uses.

☐Domestic or farm animals are known to defecate, regurgitate or discard viable plant material or to spread it on feathers, hair, skin or feet, eg due to stickiness, small seed size or the presence of hooks.

☐Occasionally, viable plant material is spread via domestic or farm animals.

☐The species is not known to be spread via domestic or farm animals.

☐The ability for the parent species to be spread via domestic or farm animals is unknown.

Provide a rationale or evidence for your answer.

Enter answer.

An example answer is available.

h. Is the parent species spread via contaminated produce?

Indicate which statement(s) about the parent species' spread via contaminated produce is most applicable. Select more than one statement if there is a difference between the relevant land uses.

☐Viable plant material is commonly spread by contaminated produce, eg in crop or pasture seed, hay, grain, soil, sand, gravel, manures or mulches; or through by-products or waste of industries such as stockfeed manufacturers or tanneries; or through seeds on or in rolled turf.

☐Occasionally, viable plant material is spread via contaminated produce.

☐The species is not spread via contaminated produce.

☐The ability for the parent species to be spread via contaminated produce is unkown.

Provide a rationale or evidence for your answer.

Enter answer.

An example answer is available.

14.9 What environmental factors (abiotic and biotic) naturally limit the spread and persistence of the parent species in the environment?

Details provided should include factors such as temperature, moisture, disease, predators and domestication (eg reduced fertility or loss of seed pod shattering) which naturally limit the spread and persistence of the parent plant in the environment.

Enter answer.

An example answer is available.

14.10 What weed management practices are typically used to restrict the spread and persistence of the parent species in each relevant land use?

Typical weed management practices refer to measures used which are intended to kill or prevent the parent species from establishing and surviving, spreading to a new location or reproducing. Practices may include the use of herbicide(s), mechanical measures (such as mowing or ploughing), crop rotation, hand pulling or other methods. The types and timing of these practices may vary between and within different environments or land uses. Describe the current weed management practices.

Enter answer.

An example answer is available.

14.11 What is the parent species' tolerance to typical weed management practices?

The effectiveness of control measures in killing the parent plant or preventing it from establishing and surviving, spreading to a new location or reproducing may determine the need and extent of additional control measures should the GM plant be released under limited and controlled conditions.

Classify the effectiveness of typical management practices used on the parent for each relevant land use. Select more than one statement if there is a difference between the relevant land uses.

☐No specific management is applied on the species in the land use.

☐Over 95% of plants survive typical weed management, ie the parent plant has very high tolerance.

☐More than 50% of plants survive, ie the parent plant has high tolerance.

☐Less than 50% of plants survive, ie the parent plant has medium tolerance.

☐Less than 5% of plants survive, ie the parent plant has low tolerance.

☐The parent plant's tolerance to standard weed management practices is unknown.

Provide supporting evidence for each relevant land use.

Enter answer.

An example answer is available.

14.12 Provide details of any State or Commonwealth restrictions on the movement of material from the parent species within and between producing regions.

Examples include restrictions on the movement of fruit and vegetables between states and/or growing regions to control spread of fruit fly and the movement of banana plants to control spread of disease.

Enter answer.

An example answer is available.

14.13 What are the standard practices to restrict the transfer of genetic material from the parent plant to other plants by sexual reproduction (if applicable)?

This information can assist evaluation of the effectiveness of the proposed controls and limits to restrict gene flow from the GM plant(s) to other plants by sexual reproduction.

Methods may be according to industry standards (such as seed certification guidelines). They may be physical, biological or a combination of both, eg isolation distances, use of selfing bags, use of sterile cultivars or the use of a triticale border around grass breeding trials.

Enter answer.

An example answer is available.

Part 15: References Cited in the Application

Include all citations in this application.

Insert reference list.

An example answer is available.