



## Application for DNIR licence

For Dealings with a GMO Not involving an Intentional Release of the GMO into the environment (contained dealings)

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### *Preliminary information*

1. a) Applicant Organisation: \_\_\_\_\_  
b) Project Supervisor: \_\_\_\_\_  
c) Project Title: \_\_\_\_\_  
d) IBC Project Identification: \_\_\_\_\_

2. Are you applying for a declaration of Confidential Commercial Information (CCI)?

Yes  No

If yes, have you attached an application for a declaration of CCI to the end of this DNIR licence application (after Part 13)?

Yes  No

If the CCI is covered by previous CCI application(s), please provide the CCI application number(s) here. \_\_\_\_\_

3. Is this application to replace existing or deemed DNIR licence(s)?

Yes  No

If yes, please provide licence or Gene Manipulation Advisory Committee (GMAC) number(s) here. \_\_\_\_\_

Time taken to complete this application:

DNIR\_0203

# Abbreviations

the Act	the <i>Gene Technology Act 2000</i> (Commonwealth)
CCI	Confidential Commercial Information
DIR	Dealings involving an Intentional Release of a GMO into the environment
DNIR	Dealings Not involving an Intentional Release of a GMO into the environment
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
IBC	Institutional Biosafety Committee
OGTR	Office of the Gene Technology Regulator
PC1, 2 <i>etc</i>	Physical Containment Level 1, 2 <i>etc</i>
the Regulations	the <i>Gene Technology Regulations 2001</i> (Commonwealth)
the Regulator	the Gene Technology Regulator

# General information about applying for a DNIR licence

## ***Application for a DNIR licence***

This application is for a DNIR licence under the *Gene Technology Act 2000* (Commonwealth) (the Act) and corresponding State law.

According to the Act, to “*deal with, in relation to a GMO, means the following:*

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

*and includes the possession, supply, use transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of (a) to (g).”*

## ***Providing information to the Office of the Gene Technology Regulator (OGTR)***

Before issuing a licence for dealings involving a GMO, the Gene Technology Regulator (the Regulator) is required, under the Act, to assess the risks posed by the dealings, including any risks to the health and safety of people or to the environment.

The information you provide in your application is used to conduct a risk assessment and develop a risk management plan in regard to the proposed dealings. The resulting risk management plan will be the basis of the conditions in a licence if issued.

It is therefore important to provide information that is as comprehensive as existing scientific knowledge permits, and supported by whatever data are available to you.

The Regulator (or the Regulator’s delegate) may require you to provide additional information and will notify you if this is required.

## ***Accuracy of information***

Please answer all questions unless otherwise indicated. Check carefully before you submit your application that all the information it contains is accurate. If the information you provide is incorrect or incomplete the Regulator’s decision about this application may be delayed or the Regulator may not issue a licence.

The Act provides for penalties to a person who gives information to the Regulator that they know to be false or misleading.

### ***Confidentiality***

If you wish to make an application for a declaration that specifies information is Confidential Commercial Information (CCI) for the purposes of the Act, you must also complete the CCI application form available at [www.ogtr.gov.au](http://www.ogtr.gov.au) and place it at the end of this application (after Part 13).

### ***Privacy***

Any personal information is safeguarded by the *Privacy Act 1988*. This prevents the submitted personal information from being used for purposes other than assessing the licence application, or other circumstances specified by the *Gene Technology Act 2000* (Commonwealth). In certain circumstances information supplied during the course of an application for a licence may, according to their specific needs, be given to the following:

- an officer or employee of the Department of Health and Ageing;
- an officer or employee of a State government agency or organisation;
- Courts, Tribunals and/or other Commonwealth agencies where it is an obligation under law to provide it;
- law enforcement authorities; and
- the relevant Minister.

Information regarding applications received by the OGTR will also be published at [www.ogtr.gov.au/gmorec/contained.htm](http://www.ogtr.gov.au/gmorec/contained.htm). This is a public record and includes, for each DNIR application, the organisation name and State, project title, a brief description of the project and the status of the application.

### ***Timeframes***

The statutory time period for the Regulator to make a decision on a DNIR application is 90 working days. A licence is generally issued for a maximum of 5 years.

If your application cannot be progressed, for example, because insufficient information has been provided, there may be a suspension of the statutory time period within which your application must be considered. This is referred to as 'stopping the clock' on the application. Should the clock stop in connection with your application, a written notice will be sent to you outlining the reasons for the suspension and what must be done in order to resume the assessment of your application.

### ***Application authorisation***

Please ensure that if you are completing this application on behalf of the proposed licence holder, that you hold the proper authority to submit this application for the proposed licence holder.

### ***Further information***

Please contact the OGTR by:

Telephone: 1 800 181 030

E-mail: [ogtr@health.gov.au](mailto:ogtr@health.gov.au)

The *Handbook on the Regulation of Gene Technology in Australia - A User's Guide to the Gene Technology Act 2000 and related legislation* and other information are available at [www.ogtr.gov.au](http://www.ogtr.gov.au).

### ***The completed application can be lodged as follows:***

1. Directly: Office of the Gene Technology Regulator  
Level 1, Pharmacy Guild House  
15 National Circuit, Barton ACT 2600
2. Mail: Office of the Gene Technology Regulator  
Commonwealth Department of Health and Ageing  
MDP 54, PO Box 100  
Woden ACT 2606
3. Fax: (02) 6271 4202 (the original to follow in the mail)

Please retain a copy of your completed application.

### ***Acknowledgment of receipt***

Once received, a DNIR number will be assigned to the application and the relevant IBC secretary will be informed. Please use this DNIR number to refer to any matters in regard to the application.

If you have not received a DNIR number within two weeks, please e-mail [ogtr@health.gov.au](mailto:ogtr@health.gov.au) or telephone 1 800 181 030.

# **Instructions on how to prepare this application**

Please save a copy of this document on your own computer system.

Insert your answers either in the space provided or underneath each question replacing the explanatory information and/or examples.

## ***Part 1***

This Part is to be completed by the Applicant organisation's representative

## ***Part 2 to 10***

These Parts are to be completed by the Project Supervisor.

## ***Part 11***

This Part is to be completed by the IBC for the proposed licence holder.

## ***Part 12***

This Part is to be completed by the Applicant Organisation's representative.

## ***Part 13***

This Part is for the required signatures from the:

- the Applicant Organisation's representative;
- Project Supervisor; and
- IBC chair.

## Part 1: Proposed licence holder

Organisation name:

Accreditation number:

### *Details of the person the OGTR can contact regarding this application*

Name:

Position:

Business telephone number:

Mobile telephone number:

Facsimile number:

E-mail address:

Street address:

Postal address:

## Part 2: Project Supervisor

Project supervisor's name:	<input type="text"/>
Position within the organisation:	<input type="text"/>
Relevant qualifications:	<input type="text"/>
Relevant experience:	<input type="text"/>

### ***Contact details of the Project Supervisor***

Business telephone number:	<input type="text"/>
Mobile telephone number:	<input type="text"/>
Facsimile number:	<input type="text"/>
E-mail address:	<input type="text"/>
Street address:	<input type="text"/>
Postal address:	<input type="text"/>

## **Part 3: About the proposed dealings with the GMO**

In this Part you are required to describe the proposed dealings with the GMO or GMOs within the context of your project. This will provide the OGTR with a clear picture of how the GMO(s) will be generated and used.

To answer the questions in this Part, please firstly remove any explanatory text and then insert your answer directly under the question.

### **3.A What is the title of the project?**

A short descriptive title that is as precise and informative as possible.

### **3.B What is the proposed date of commencement of the project?**

In considering the commencement of your work please take into consideration that DNIR applications take up to 90 working days to process.

Please also note that the proposed dealings with the GMO(s) cannot commence until the Regulator has issued a licence authorising the dealings.

### **3.C What is the proposed date of completion of the project?**

The completion date will reflect a reasonable timeframe for the project. Licences are generally issued for a maximum of 5 years duration.

### **3.D Who are the people or class of people who will be authorised to undertake dealings with the GMO(s)?**

“Class of persons” includes PhD students, technical officers *etc.*

### **3.E What are the aim(s) of the project?**

Describe the specific aims of the project involving the proposed dealings.

### **3.F Briefly describe the project in no more than one or two sentences using plain English and non-technical terms.**

This brief description of your project, together with the project title, name of the organisation and status of the application will be placed on the OGTR web site at [www.ogtr.gov.au/gmorec/contained.htm](http://www.ogtr.gov.au/gmorec/contained.htm). This is a public record of the DNIR applications received by the OGTR.

### **3.G What is the scientific background to the project?**

Write about the scientific background of your project. Please do not write more than one page. Also submit copies of key papers as this may assist the assessment process (see also Part 10: References).

### **3.H What is the experimental plan?**

The purpose here is to describe the proposed dealings using an outline of the experiments to be conducted, including experimental design and techniques to be used (but not detailed protocols). Please also include, if appropriate, the acquisition and the proposed fate of all GMO(s) at the completion of the dealings.

You may use dot points in your answer and please do not write more than one page.

## Part 4: Description of the GMO

The information requested in Parts 4 to 8 is required to help identify any possible hazards associated with the proposed dealings with the GMO or GMOs. Some questions in Parts 4 to 8 may also relate to risk assessment and risk management, which are addressed in Part 9.

In the previous section you will have generally described the GMO(s) within the context of your project.

In Part 4, a more specific description of the GMO(s) is required. This includes a description of all the GMO(s) to be generated and/or used during the proposed dealings, for example, bacteria used for subcloning steps, tissue culture cell lines *etc.*

Please replace any explanatory text with your answers. Alternatively, you may choose to present this information in a table (refer to the examples in Table 2 at the end of Part 4). A blank table has also been provided at the end of this Part.

### **4.A What are the common and scientific names of the parent organism(s)?**

The “parent organism” means the organism (or tissue derived from organisms) that you propose to genetically modify.

### **4.B What vector(s) or methods are to be used for the transfer of genetic material?**

Please provide copies of references (or vector maps) for novel vectors or methods of transfer. Also include the name of the company supplying any commercially obtained vectors.

### **4.C Are any of the proposed host/vector systems to be used not listed as an exempt dealing in Part 2 of Schedule 2 of the Gene Technology Regulations 2001 (the Regulations)?**

In this case, “host” equates to “parent” as described in Part 4.A above.

If not an exempt dealing, please provide the reasons why it is not.

### **4.D What is the class of the modified trait(s)?**

Select from Table 1 below the class of trait that will be modified in each parent organism. This will aid in the collection and management of statistical information about dealings with GMO(s) in Australia. Refer to Table 2 at the end of Part 4 for examples.

**Table 1**

<b>Class of trait</b>
Abiotic stress resistance
Altered agronomic characteristics
Altered nutritional characteristics
Altered pharmaceutical characteristics
Altered physical product characteristics
Antibiotic resistance
Foreign antigen expression
Attenuation
Bacterial resistance
Disease resistance
Flower colour
Fungal resistance
Herbicide tolerance
Immuno-modulatory protein expression
Pest resistance eg insect
Protein expression
Reporter/marker gene expression
Virus resistance
Other (provide details)
Unknown

**4.E What are the modified trait(s)?**

**4.F What are the identity and function of the gene(s) responsible for the modified trait?**

In terms of identifying any possible hazards, the primary interests here are in the gene(s) under study and the function of these gene(s). Please list this information if known.

Such details are not required about gene(s) commonly used as markers, for selection and/or any other routine procedures. However it is of interest to identify generally which of type of gene will be used. For example, *amp* gene (ampicillin resistance), *neo* gene (neomycin resistance), *gfp* gene (green fluorescent protein) *etc.*

The level of detail that is required is outlined in Table 2 at the end of Part 4.

**4.G From what organism were the gene(s) responsible for the modified trait(s) isolated?**

In regards to gene(s) commonly used as markers, for selection and/or any other routine procedures, please indicate the plasmid from which these

gene(s) were derived. The level of detail that is required is outlined in Table 2 at the end of Part 4.

**4.H What are the organisms or tissues to be used in association with the GMO(s)?**

Please list all the organisms you intend to use in association with the GMO(s), for example, animals to be inoculated or fed with the GMO(s). Another example would be bacteria that have been genetically modified are placed into a mouse to test pathogenicity. In this case 'mouse' must be listed here.

Note that if animals, plants or people are involved in these dealings, please complete either Part 6, Part 7 or Part 8 respectively.

**4.I Is there any further information that you are aware of regarding the nature of the GMO(s)?**

Information that you provide here will help to reduce the level of the uncertainty in the risk assessment.

Examples of additional information:

- the site within the parent organism's genome where the genetic modification has taken place; or
- that a gene is known to have been disrupted due to the insertion of another gene.

**Table 2 - Examples of responses to Part 4: The description of the GMO(s)**

The “parent organism” means the organism(s) (or tissue derived from organisms) that you propose to genetically modify and “host” equates to “parent”.

4	4.A		4.B	4.C	4.D	4.E	4.F and 4.G	4.H
GMO	Common name of parent organism	Scientific name of parent organism	Vector(s) or method of transfer	Exempt Host/vector system?	Class of modified trait (refer to Table 1)	Modified trait	Identity and function of gene(s) and organism of origin	Organisms or tissues to be used with the GMO(s)
1	human cell line	293	transduction by recombinant retroviral vector pLXSN	no (provide reasons why)	antibiotic resistance	resistance to neomycin	<i>neo</i> gene from pLXSN (Stratagene)	<i>Mus musculus</i>
					protein expression	expression of CD44 receptor	CD44 (transmembrane signalling molecule) gene from <i>homo sapiens</i>	
					reporter gene expression	fluorescence (expression of Green Fluorescent Protein or GFP)	<i>gfp</i> gene from <i>Aequorea victoria</i>	
2	mouse retroviral packaging cell line (amphotropic)	PA317 mouse embryo fibroblast	CaPO <sub>4</sub> transfection of pLXSN	no (provide reasons why)	antibiotic resistance	resistance to neomycin	<i>neo</i> gene from pLXSN (Stratagene)	none
					protein expression	expression of CD44 receptor	CD44 (transmembrane signalling molecule) gene from <i>homo sapiens</i>	
					reporter gene expression	fluorescence (expression of GFP)	<i>gfp</i> gene from <i>Aequorea victoria</i>	

4	4.A		4.B	4.C	4.D	4.E	4.F and 4.G	4.H
GMO	Common name of parent organism	Scientific name of parent organism	Vector(s) or method of transfer	Exempt Host/vector system?	Class of modified trait (refer to Table 1)	Modified trait	Identity and function of gene(s) and organism of origin	Organisms or tissues to be used with the GMO(s)
3	mouse retroviral packaging cell line (ecotrophic)	Psi-2 mouse embryo fibroblast	CaPO <sub>4</sub> transfection of pLXSN	yes	antibiotic resistance	resistance to neomycin	<i>neo</i> gene from pLXSN (Stratagene)	none
					protein expression	expression of CD44 receptor)	CD44 (transmembrane signalling molecule) gene from <i>homo sapiens</i>	
					reporter gene expression	fluorescence (expression of GFP)	<i>gfp</i> gene from <i>Aequorea victoria</i>	
4	bacteria	<i>Escherichia coli</i>	pBR322 by electro-poration	yes	antibiotic resistance	resistance to ampicillin	<i>amp</i> gene from pBR322	none
					unknown	uncharacterised	uncharacterised genes from <i>Mus musculus</i>	

The Table below can be used to enter your answers.

The “parent organism” means the organism(s) (or tissue derived from organisms) that you propose to genetically modify and “host” equates to “parent”.

4	4.A		4.B	4.C	4.D	4.E	4.F and 4.G	4.H
GMO	Common name of parent organism	Scientific name of parent organism	Vector(s) or method of transfer	Exempt Host/vector system?	Class of modified trait (refer to Table 1)	Modified trait	Identity and function of gene(s) and organism of origin	Organisms or tissues to be used with the GMO(s)
1								
2								

## Part 5: Additional information if the volume of GMO culture exceeds 10 litres

The following information is required if you propose to produce a culture of GMO exceeding 10 litres in volume. This could also include a number of cultures of a GMO grown at one time that are each less than 10 L but the volumes in total exceed 10 L.

Applicable

Not applicable

Please provide enough detail in your answers so that a clear picture of the proposed dealings is obtained.

Copies or summaries of any protocols and/or standard operating procedures can be included to specifically answer the individual questions.

To answer the questions in this Part, please firstly remove any explanatory text and then insert your answer directly under the question.

**5.A What is the volume of GMO culture to be produced and how often will the cultures be generated?**

**5.B What are the main product(s) to be isolated?**

**5.C What are the processing steps to be taken in order to purify these product(s)?**

If known, please indicate the viable GMO cell counts at each processing stage including in any effluent.

**5.D Will the genetic stability of the GMO be checked? If yes, how will this be done and at what frequency?**

This relates to monitoring strategies to detect possible mutations, recombinations or other unforeseen effects.

**5.E Is the facility to be used a certified PC2 large-scale facility?**

If not, please provide justification for the containment level proposed and details of the facility to be used for the proposed project, including how the physical containment of the GMO is to be achieved, particularly during handling.

**5.F What precautions will be taken to prevent any unintended dispersal of the GMO?**

## **Part 6: Additional information for a GMO that is a whole plant or is to be used in conjunction with a whole plant**

The following information is required if you propose to deal with a GMO that is a whole plant or is to be used in conjunction with a whole plant.

Applicable

Not applicable

Please provide enough detail so that a clear picture of the proposed dealings is obtained.

Copies or summaries of any protocols and/or standard operating procedures can be included to specifically answer the individual questions.

To answer the questions in this Part, please firstly remove any explanatory text and then insert your answer directly under the question.

**6.A Is the parent organism (that which is to be modified) a weed or closely related to plants that are weeds?**

If yes, please identify any closely related weeds.

**6.B To what stage of development are the plants to be grown?**

This relates to the potential spread of the GMO, for example, if the plant produces pollen or seed.

**6.C What will be the methods of disposal of the plants?**

**6.D What measures are proposed to prevent the dissemination of pollen and seeds?**

**6.E What will be used as the growing medium for the plants?**

Please indicate the type of medium (soil or soil substitute) to be used and how it will be subsequently sterilised or disposed of.

## **Part 7: Additional information for a GMO that is an animal or is to be used in connection with an animal**

The following information is required if you propose to deal with a GMO that is an animal or is to be used in connection with an animal.

Applicable

Not applicable

Please provide enough detail so that a clear picture of the proposed dealings is obtained.

Copies or summaries of any protocols and/or standard operating procedures can be included to specifically answer the individual questions.

To answer the questions in this Part, please firstly remove any explanatory text and then insert your answer directly under the question.

**7.A What is the number of genetically modified animals and/or the number of other animals to be used?**

**7.B What are the proposed arrangements for breeding the animals or for ensuring that the animals do not breed?**

Please include strategies to prevent the escape of animals from the facilities.

**7.C How will the animals be identified?**

Examples include the use of labels on cages or, for larger animals, branding or tattooing.

**7.D Have you applied for Animal Ethics Committee approval for the proposed dealings?**

If yes, please provide the name of the committee and, if approved, the date of approval.

## **Part 8: Additional information for a GMO that is for use in clinical trials with human beings**

The following information is required if you propose to deal with a GMO or GMOs for use in clinical trials with human beings (as a vaccine or, in a gene therapy trial, as a vector).

Applicable

Not applicable

Some questions below cover the dissemination of the GMO(s). These are asked in order to confirm that the proposed dealings are a DNIR. If viable GMO(s) are likely to be spread by the recipients, then a licence for Dealings involving Intentional Release of a GMO into the environment (DIR) application for the proposed clinical trial will need to be submitted.

Please provide enough detail so that a clear picture of the proposed dealings is obtained.

Copies or summaries of any protocols and/or standard operating procedures can be included to specifically answer the individual questions.

To answer the questions in this Part, please firstly remove any explanatory text and then insert your answer directly under the question.

**8.A What is the disease to be treated, or prevented, by use of the GMO?**

**8.B What is the host range of the parent organism(s) from which the vaccine or vector is constructed?**

**8.C What is the potential for the genetic material of the vaccine organism or gene therapy construct to become incorporated in whole, or in part, into the genome of any cells of a treated person?**

This is in regard to the potential for somatic cell mutation possibly resulting in hazards to the health of people being treated.

**8.D What factors will prevent multiplication or spread of the vaccine organism or the vector in a treated person?**

**8.E How long will the GMO be detectable in a person or their excretions and will it be viable?**

**8.F What is the potential for the GMO to be disseminated into the environment through human excretions and wastes during or after the trial?**

Include, but do not limit to, information on:

- the potential for their dissemination through close personal contact, or to the general population;
- measures intended to be taken to minimise the potential for dissemination;
- the potential for the GMO to cross the placenta of a pregnant person or animal;
- the potential for the GMO to spread to other species; and
- if the potential exists, the likely mechanism and frequency of such spread.

**8.G If the GMO is a defective virus, what is its potential for acquiring the capacity for viral replication by complementation or recombination with intracellular viruses?**

**8.H Are there any deleterious effects that the GMO may have on a pregnant person? If yes, please provide details.**

**8.I Does the GMO have a teratogenic effect on a foetus at any stage of gestation? If yes, provide details of the effect?**

**8.J Could a person who undergoes the treatment be more susceptible to an adverse outcome because of:**

- a) the state of health of the person at the time of treatment (for example, the person presents with immunosuppression or superimposition of disease); or
- b) other treatments, such as drugs?

**8.K Is the use of the GMO likely to preclude its use for vaccination against other diseases subsequently?**

**8.L Does the GMO produce spores and what is their viability if desiccated?**

**8.M What are the proposed methods for sterilisation and disposal of waste containing the GMO?**

Please include strategies for preventing the escape of the GMO into the environment and the effectiveness of these strategies. Also indicate which sterilising and anti-microbial agents (if any) are active against the GMO.

**8.N Have you sought advice from the Gene and Related Therapies Research Advisory Panel (GTRAP) for approval for the proposed dealings?**

Please provide the date of approval and the advice provided.

## Part 9: Risk assessment and management

In Parts 4 to 8 you will have provided information that will help to identify any possible hazards associated with the proposed dealings as well as some risk assessment and risk management information. This information can be used to answer the questions in this Part.

The preparation of the risk assessment involves identifying any possible hazards that may be posed by the GMO or GMOs and the level of risk posed by such hazards based on an assessment of the likelihood and consequence of the hazard occurring. The risk assessment investigates whether the genetic modification has created or increased any risk over and above those posed by the parent organism.

The risks that the Regulator is required to assess are:

- risks to the health and safety of people from the genetic modification;
- risks to the health and safety of people from an unintentional release of the GMO(s); and
- risks to the environment from an unintentional release of the GMO(s).

The risk management plan details how any risks posed by the GMO(s) will be managed to ensure that unacceptable risks are not realised.

Copies or summaries of any protocols and/or standard operating procedures can be included to specifically answer the individual questions.

To answer the questions in this Part, please firstly remove any explanatory text and then insert your answer directly under the question.

**9.A In regard to the health and safety of people, what are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (ie the risk) from the proposed genetic modification(s)?**

This relates to the occupational health and safety of people undertaking the dealings, for example, laboratory staff working in labs. If appropriate, include comparisons to the unmodified organism.

**9.B In regard to the health and safety of people, what are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (ie the risk) from an unintentional release of the GMO(s) into the environment?**

This relates to the general population exposed to a GMO that is unintentionally released from containment. If appropriate, include comparisons to the unmodified organism.

For viruses, include, but do not limit to, information on:

- if it is replication deficient and, if so, what are the modifications responsible for this;
- the replication properties in different cells and organisms;
- infection capability irrespective of its ability to replicate; and
- information about complementation and recombination.

**9.C In regard to the environment, what are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (ie the risk) from an unintentional release of the GMO(s) into the environment?**

This relates to the environment exposed to a GMO that is unintentionally released from containment. If appropriate, include comparisons to the unmodified organism.

**9.D Have applications (whether successful or unsuccessful) been previously made under the Act, or to the Genetic Manipulation Advisory Committee (GMAC), in relation to a proposed dealings with the GMO?**

The details required are:

- reference number provided by the OGTR or GMAC;
- title of project;
- date of application; and
- project supervisor

This information can be tabulated if there are multiple applications as indicated in Table 3 below.

**Table 3**

<b>Reference number</b>	<b>Title of project</b>	<b>Date of application</b>	<b>Project supervisor</b>

**9.E On the next page, please provide information for all of the facilities to be used.**

### ***The facility***

Name of facility:	<input type="text"/> <i>(This will be the same as that on the notice of certification)</i>
Facility type:	<input type="text"/> <i>(For example, animal containment facility, laboratory, insect containment facility etc)</i>
Physical containment level:	<input type="text"/> <i>(PC2, PC3, PC4 etc)</i>
Date of certification:	<input type="text"/>
Certification number:	<input type="text"/>
Date of most recent inspection:	<input type="text"/>
Who undertook the inspection:	<input type="text"/> <i>[Indicate if it was the OGTR or the IBC (or its representative)]</i>

### ***Facility address details***

Street address:	<input type="text"/>
-----------------	----------------------

### ***Facility contact person details***

Name:	<input type="text"/>
Business phone number:	<input type="text"/>
Mobile phone number:	<input type="text"/>
Facsimile number:	<input type="text"/>
E-mail address:	<input type="text"/>

If you are using more than one facility you may tabulate the information as in Table 4 below.

**Table 4**

<b>Information required</b>	<b>Facility 1</b>	<b>Facility 2</b>
Name of facility		
Facility type		
Physical containment level		
Date of certification		
Certification number		
Date of most recent inspection		
Facility address details		
Facility contact person details		

**9.F Do you propose to transport the GMO(s) outside a certified facility?**

If you propose to transport the GMO(s) please indicate why it will be required and what arrangements will be made. Transport includes: between the facilities listed in your answer to Part 9.E; from a laboratory to an autoclave or animal house; across corridors which are not part of a certified facility *etc.*

**9.G How will the GMO(s) be disposed of?**

This includes arrangements for disposing of the carcasses of all animals inoculated with GMO(s), and liquid and solid waste from the dealings.

**9.H How do you propose to decontaminate equipment used during the proposed dealings in order to render any GMO(s) unviable?**

**9.I What are the steps in your contingency plan in the case of an unintentional release of the GMO(s)?**

In general, the steps must cover how:

- the unintentional release will be contained and people protected;
- the area and any people will be decontaminated;
- the contaminated material will be disposed of; and
- the incident will be reported.

Also include here contingency plans to deal with the escape of any animals to be used during the proposed dealings.

Note that it is required in the Act that the Regulator must be notified if there has been an unintentional release of the GMO from containment.

**9.J Are there any other actions and precautions you will take to minimise risks posed by the proposed dealing(s)?**

These refer to precautions that are over and above that outlined in PC2 procedures or guidelines. For example, when using pathogenic organisms during the genetic modifications it may be required that, in addition to working in a biological safety hood, gloves will also be required for all manipulations.

**9.K What steps will you take to notify all persons covered by the licence issued by the Regulator of the licence conditions?**

## **Part 10: References**

Insert your list of references here. Please provide copies of key references and place these after your list of references (before Part 11).

## Part 11: IBC evaluation of this application

Note that a separate *IBC Evaluation Form* is not required if Part 11 is completed.

If a risk assessment has been carried out please provide a copy after Part 11.

Insert any additional information under the question to be answered.

### ***IBC Details***

Name of IBC:	<input type="text"/>
Name of IBC Chairperson:	<input type="text"/>
Business telephone number:	<input type="text"/>
Mobile telephone number:	<input type="text"/>
Facsimile number:	<input type="text"/>
E-mail address:	<input type="text"/>

Name of IBC Secretary:	<input type="text"/>
Business telephone number:	<input type="text"/>
Mobile telephone number:	<input type="text"/>
Facsimile number:	<input type="text"/>
E-mail address:	<input type="text"/>

### ***IBC evaluation of application***

11.A Date of IBC evaluation: \_\_\_\_\_

11.B 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

**11.C Has the information contained in the Preliminary Information and Parts 1–10 been checked by the IBC and found to be complete?**

Yes  No

**11.D Does the IBC consider that the personnel to be involved in the proposed dealings with the GMO(s) have adequate training and experience for the task?**

Yes  No

**11.E Is this application appropriately classified as a DNIR application?**

Yes  No

**11.F What level of containment is appropriate for these dealings?**

PC2

PC3

PC4

Other (please specify): \_\_\_\_\_

**11.G What facility, or facilities, are appropriate for these dealings?**

Laboratory

Animal Containment

Plant House

Other (please specify): \_\_\_\_\_

**11.H Are there any additional conditions the IBC considers must be adhered to during the conduct of the proposed dealings?**

## Part 12: Suitability of the proposed licence holder

**12.A Has information regarding the proposed licence holder's financial viability (for example, an annual report) been recently submitted to the OGTR?**

Yes  No

If yes, please provide the application number with which these documents were submitted.

Application number: \_\_\_\_\_

If no, please either provide these documents at the end of Part 12 or provide an Internet address below for access to such documents.

Internet address: \_\_\_\_\_

Please note that "annual report" does not refer to the *Accredited Organisation Annual Report to the Gene Technology Regulator*.

**12.B Have there been any relevant convictions of the proposed licence holder and/or the Project Supervisor?**

Proposed Licence Holder  Yes  No

Project Supervisor  Yes  No

According to the Act, "**relevant conviction** means a conviction for an offence against 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, if:

- (a) the offence was committed within the period of 10 years immediately before the making of the application for the licence; and
- (b) the offence was punishable on conviction by a fine of \$5,000 or more, or by a term of imprisonment of one year or more."

If this applies, please provide details at the end of Part 12.

**12.C Has there been any failure by the proposed licence holder to comply with:**

- (a) a provision of the Act or Regulations; or
- (b) a condition of a licence or permit (particularly if resulting in a revocation or suspension) held under a law relating to the health and safety of people and the environment?

Yes  No

If yes, please provide details at the end of Part 12.

**12.D Have there been any failures by the proposed licence holder to comply with an advice to proceed issued by the GMAC?**

Yes  No

If yes, please provide details at the end of Part 12.

**12.E Is there any other information you can provide to the Regulator that is relevant to making a decision on this application?**

Yes  No

If yes, please provide details at the end of Part 12.

## Part 13: Signatures

I declare that to the best of my knowledge, having made reasonable inquiries, the information herein is true and correct. I understand that providing misleading information to the OGTR, deliberately or otherwise, is an offence under Commonwealth law.

### ***Applicant organisation's representative***

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

### ***Project Supervisor***

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

### ***IBC Chair***

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_