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

Application for a licence

for importation and processing of bulk grain

[Qualifying as dealings with a GMO not involving intentional release of the GMO into the environment (DNIR)]

Applicant organisation name:	Enter name
Origin of the grain to be imported:	Enter answer
Crop species (e.g. corn):	Enter species name

Guidance notes: This licence category requires the imported grain to be transported securely and kept in appropriate containment facilities (e.g. an Approved Arrangement site under the *Biosecurity Act 2015*) until it is devitalised (i.e. rendered non-viable).

Time taken to complete this form: Enter hours Enter minutes

Information for applicants

We encourage prospective applicants to contact the Office of the Gene Technology Regulator (OGTR) before submitting an application to advise you on the classification of GMO dealings and in selecting the appropriate application form, and to discuss information requirements. You can call (1 800 181 030) or email.

What is this application form for?

This application form must be used for applications for a licence for importation and processing (devitalisation) of bulk grain containing GMO(s) that are authorised for cultivation and/or food/feed use in the country of origin.

Import and processing of bulk grain are 'dealings NOT involving the intentional release (DNIR) of a GMO into the environment' in accordance with section 46 of the *Gene Technology Act 2000* (the Act). This is providing that the grain is transported securely and kept in appropriate containment facilities (e.g. an Approved Arrangement (AA) site under the *Biosecurity Act 2015*) until it is devitalised (i.e. rendered non-viable).

The dealings that can be authorised via this application type are restricted to:

- import of the GMO
- transport and disposal of the GMO
- use of the GMO in the course of manufacture of a thing that is not the GMO (i.e. processing)

and possession of the GMO for the purpose of, or in the course of, any of the above.

Who will be covered by the licence?

Subject to a licence being issued, the organisation applying for the licence will be the licence holder. Licence conditions apply to persons covered by the licence. Such persons may include employees, contractors or agents of the licence holder.

How will the provided information be used?

We will use the information in the application form to prepare a Risk Assessment and Risk Management Plan (RARMP) for the proposed activities. The decision by the Gene Technology Regulator (the Regulator) on whether or not to issue a licence, and conditions to impose if a licence is issued, is based on the RARMP.

Information in this application may be provided to other Federal or State government agencies or to experts as part of the Regulator's evaluation of the application, and it may be released to the public under certain limited circumstances, e.g. in response to a Freedom of Information request.

What is the application fee for a DNIR application?

There is currently no application fee.

How should you fill out this form?

- We prefer you sending your application electronically in a searchable format.
- Ensure you answer each relevant question in sufficient detail. Not providing the required information could delay a decision, or the Regulator may not consider your application (section 43 of the Act).
- Ensure you answer each question to the best of your knowledge. Deliberately providing false or misleading information is a punishable offence (section 192 of the Act).
- Ensure you answer each question with adequate supporting material. Scientific information should be comprehensive and supported by whatever data and references are available.
- 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.

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.

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 DNIR licence application within 90 working days.

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

Disclosure of information

With the exception of personal, security sensitive or confidential commercial information, details of licences issued by the Regulator will be published on the OGTR website.

Table of Contents

Personal Information

Personal information is collected by the OGTR to enable the Regulator to perform the functions set out in 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 (APPs) set out in the *Privacy Act 1988*. More information can be accessed at the OGTR's privacy and personal information web page. The OGTR's 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.

Personal title, e.g. 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: 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.

2.1 This application is being made by:

☐ a natural person (you personally are proposing to hold the licence) (proceed to Part 3)

☐ an organisation

2.2 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, i.e. 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 3: 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.

3.1 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

3.2 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

3.3 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

3.4 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.

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

Enter details

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

Select date

3.6 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, e.g. by providing the URL for the statement on the internet.

Enter URLs or attachment numbers

3.7 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

3.8 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 unloading the GM seeds from the ship at the port of discharge
- persons transporting the GM seeds, e.g. drivers of conveyance
- persons destroying the GMO, e.g. at crushing facilities.

Enter details

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 obtain 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

Part 4: Description of the GMO(s)

Provide a list of all the GMOs which may be included in the proposed grain import. If more than one crop species is to be imported, use a separate table for each crop species.

Note: please clearly list all the GM lines (also referred to as GM events) that may be included in your proposed bulk grain import. A link to a website only is not considered as adequate. Add more rows in the table to add more GM lines if necessary.

Crop species: Enter both common and scientific names

GM line (event)*	Prior authorisation type(s)	OGTR reference number	Name of approving authority and link for prior authorisation by another Australian agency#	Name of approving authority, reference number and link for authorisation in country of origin or other countries#
	☐ OGTR licence			
	☐ Cultivation			
	☐ Food			
	☐ Feed			
	☐ OGTR licence			
	☐ Cultivation			
	☐ Food			
	☐ Feed			

* Please also include OECD Unique Identifier if available.

For GMOs that have not been previously authorised by the Regulator, links to other authorisations must provide details of the genetic modification and resulting traits. If this information is not available on-line, please provide details of genetic modifications and traits in an attachment.

Crop species: Enter both common and scientific names

[Add new table]

Part 5: About the Dealings with the GMO(s)

In this part you are required to describe what you intend to do with the GMO(s) proposed to be authorised by the licence. This will provide the Regulator with the context for preparing a Risk Assessment and Risk Management Plan.

5.1 How long do you want the licence for?

Note: A licence is issued for a maximum of 5 years, but can be renewed.

Enter answer

5.2 What are your proposed dealings with the GMOs?

Please select from the following list of dealings:

☐ Import the GMO

☐ Use the GMO in the course of manufacture of a thing that is not a GMO

☐ Transport the GMO

☐ Dispose of the GMO

Note: If you intend to conduct other dealings with the GMO such as making a new GMO(s) or propagating the GMO(s), you may require a different type of approval. Information regarding types of authorisations can be found on the OGTR website.

Please provide more details about what you intend to do:

Enter details

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

☐ Yes ☐ No

*If you answered yes to this question you may require a licence for a Dealing involving an Intentional Release of GMOs into the environment (DIR). Information regarding DIR licences can be found on the OGTR website.

5.4 How will transport be conducted to ensure containment of the GMO (from the site where the GMO is unloaded to transport, storage and processing)?

Enter answer

5.5 How will the grain be processed to ensure devitalisation?

Enter answer

5.6 What product will be produced from the GMOs (e.g. stockfeed pellet)?

Enter answer

5.7 How will the waste GMO be disposed of/destroyed?

Enter answer

5.8 What are the steps in your contingency plan in case of an unintentional release of the GMO(s) (e.g. spill during unloading or transport)?

Enter answer

Part 6: Physical Containment of the GMO(s)

6.1 What facilities do you propose to use for the dealings?

Name	Type (e.g. *storage, processing etc.)*	Location (including street address)	AA class* (e.g. 2.7, 3.1 etc.)

*Refer to the Requirements for Operating Approved Arrangements of the Department of Agriculture)

6.2 Access and control:

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.

What relevant information can you provide about access and control of each of the proposed facilities?

Note: this may include contracts, agreements, or other enforceable arrangements.

Enter details

Part 7: Declaration

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