Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

Application for Declaration

that specified information is confidential commercial information (CCI)

1. Applicant organisation name:	Enter name
2. Accreditation number: (If the organisation is accredited by the Gene Technology Regulator.)	Enter number
3. Usually, *Applications for declaration that specified information is CCI* are for information that has been included in another application. Does this application accompany	☐ a DIR licence application ☐ a DNIR licence application ☐ a Certification application ☐ an Accreditation application ☐ a Notifiable Low Risk Dealing notification ☐ an application for a licence transfer, variation, surrender or suspension **OR** ☐ a document not listed above?
Provide the OGTR reference number, if known, for the application, notification or other document referred to in 3, e,g. DIR no.	Enter the OGTR reference number, if known
Provide the title of the application, notification or other document	Enter title
Time taken to complete this form (optional):	Enter time taken

General Instructions

Application for declaration that specified information is CCI

The completion of this form indicates you are applying for a declaration that specified information is Confidential Commercial Information (CCI) under the *Gene Technology Act 2000* (the Act). The Gene Technology Regulator (the Regulator) needs the information you provide in this form to assist in determining whether or not to make such a declaration.

All sections, parts and questions must be completed unless otherwise directed on the form. If the spaces provided are not sufficient to set out the requested information, you should attach additional information and clearly mark on the attachment which section, part and question the information relates to. You should also indicate against the item that there is additional information attached, noting the attachment title/number and the page number(s).

The Regulator may also require you to provide additional information. If this is necessary you will be notified in writing of the additional information required.

The information you provide in this application must also be true and accurate. The Act (and corresponding state law) provides for imprisonment and fines where a person gives information to the Regulator that the person knows to be false or misleading.

If the information you provide is incorrect or incomplete the Regulator's decision about this application may be delayed. It may also delay consideration of an application for a licence, certification or accreditation to which the specified information relates.

Associated DIR and DNIR Licence applications

Where applicable, this *Application for Declaration that specified information is CCI* must be submitted with a DIR or DNIR licence application to which the requested CCI relates.

Authorisation

The application must be signed by a person authorised to sign on behalf of the organisation.

Application of security markings

Under the Gene Technology legislation, the Regulator can declare as CCI only information meeting certain criteria (see section 185 of the Act). As per the Government's Protective Security Policy Framework, this information must be assigned a dissemination limiting marker of 'Sensitive' and must be conspicuously marked. Therefore, you may wish to appropriately annotate documents for which you have editor access yourself as follows:

1. If you choose to annotate, please ensure that the header and footer of all pages contain the word 'Sensitive', formatted to be at least 5 mm in height (i.e. 24 point or greater font size), bolded, centred and coloured red, e.g.

Sensitive

AND

2. Either insert a cover page at the beginning of the document or a first page footer with the following statement describing the reason for the 'Sensitive' marking and the handling requirements for the document:

CONFIDENTIAL COMMERCIAL INFORMATION (CCI)
Information in this document has been assigned a Dissemination Limiting Marker (DLM) of 'Sensitive' and is information subject to Section 185 of the *Gene Technology Act 2000* (the Act) and may only be used and accessed subject to the provisions of the Act.

If any document containing information, which is claimed to be CCI, is not appropriately marked, you MUST clearly indicate on the document that it contains information to be treated as 'Sensitive'. Staff in the OGTR will apply the relevant security markings as soon as practicable.

Lodging the application

Once you have completed the form, including the relevant signatures, you can submit it by:

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

We prefer electronic submission of an application. Please keep a copy of the application for your records.

If this form contains sensitive information (such as CCI) we recommend contacting our office prior to submitting an application for declaration of CCI 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. However, within a reasonable time of receipt of the application, staff in the OGTR will securely store the sensitive information as appropriate.

Acknowledgement of receipt and further information

You will receive an acknowledgment within two weeks of submission. If you have not received an acknowledgment from us confirming receipt of your application within two weeks, or if you have any questions about how to complete this form, please email ogtr.applications@health.gov.au or call 1800 181 030.

Information remains CCI until revoked by the Regulator

Once information is declared to be CCI, it remains CCI until the declaration is revoked by the Regulator. Therefore, it is not necessary to re-apply each time the same information is provided to the Regulator. However, in any subsequent licence application please highlight information that has previously been declared as CCI.

If the CCI status of previously declared CCI has changed so that the information is no longer commercially sensitive, you should notify the Regulator.

Personal Information

Personal information is collected by the OGTR to enable the Gene Technology Regulator to perform the functions set out under 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 (APP) 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.

Section 1: Authorised person for the application

Please provide details for a person who is authorised to act on behalf of the applicant for this application. An OGTR evaluator may contact this person with any queries about this application.

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

Section 2: Information in support of the application

The Regulator must be able to readily recognise the information for which the *Declaration that specified information is CCI* is sought. This is necessary so that the information can be evaluated and, if declared CCI, protected.

Note that a CCI declaration relates to information, not to specified text in a particular document. Once declared, information will remain CCI in other forms, parts of text, documents or contexts. Therefore, it is very important that the application precisely identifies and characterises the information for which the CCI declaration is sought, as well as specifying blocks of text in which the information is embedded in any document.

Section 2, Part A requires that you identify the sensitive information.

Section 2, Part B requires that you provide a justification for your request that information be declared CCI. You must satisfy the Regulator that the information you specify is:

- a trade secret; or
- any other information that has a commercial or other value that would be, or could be reasonably expected to be destroyed or diminished if the information were disclosed; or
- other information that concerns the lawful commercial or financial affairs of a person, organisation or undertaking and if it were disclosed, could unreasonably affect the person, organisation or undertaking.

Section 2, Part C requires you to provide additional information if your application relates to field trials.

Section 2, Part D allows you to provide details of any prejudice that would be caused to a person by disclosure of the information.

The Regulator may refuse to declare that information is CCI if satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person.

Section 2, Part A: Information in relation to which a declaration is sought

Provide responses to the questions below and include any additional information and copies of relevant documents.

Question A1: Which documents contain information over which you are seeking a declaration of CCI?

List all documents within which there is information over which you are seeking a declaration of CCI. Include the title, date and author for each document.

For example, if a DIR licence application and two reports contain information for which you are seeking a declaration of CCI, you must list those three documents and provide the full reference for each document.

List all documents containing sensitive information over which you are seeking a declaration of CCI [add title, author and date for each document].

Question A2: What is the specific information for which you are seeking a declaration of CCI?

You may wish to apply for a declaration in respect of several pieces of information, each of which requires a different and discrete justification.

Precisely describe the information for which a declaration of CCI is sought in your answer below. Also, in your answer precisely name each instance where sensitive information occurs in each of the documents listed in A1. Ensure that title, date and author of each document you are referring to match those in A1.

Be specific about the information for which you are applying for a declaration of CCI. Note that identifying an entire document, or indeed an entire table or block of text in a document, as information in relation to which a declaration is sought will require the Regulator to ask for clarification. This will delay processing of your application or may lead to the Regulator to not consider, or cease to consider, an associated DIR or DNIR licence application, if applicable.

For example:

- The identity and name of gene ZmX-1 in connection with DIR licence application *Field trial of GM cotton genetically modified for herbicide tolerance*. This application was submitted to the Regulator with this CCI application form by A COMPANY. Mention of this gene is in the answers to questions 1.4 and 1.5 on page 4 and in the answer to question 2.1 on page 8. It is also mentioned in the unpublished report *Title* by AUTHOR et al., 2013 in paragraph 5 on page 2 and in paragraph 28 on page 3.
- The details of gene construct construct-1, including its DNA sequence, origin and order of sequence elements, as listed in paragraph 226 on page 28 and in figure 3 on page 12 of *Document A* by AUTHOR2, 2011.
- The phenotype produced in the GM canola by introduction of the gene construct *construct2*, as described in paragraph 118 on page 23 and in rows 4 and 5 in table A on page 23, of the DIR licence application *Field trial of wheat genetically modified for improved nitrogen use efficiency*, submitted to the Regulator with this CCI application by A COMPANY.
- The statement of fact xyz, which is made in paragraphs 7 including 9 on page 32 of *Document D* by AUTHOR et al., 2013.
- The experimental methods pertaining to the names and DNA sequences of the primers used in the PCR reaction to test for GM sugarcane XXX-007 as set out in the unpublished report *W* by AUTHOR et al., 2009.

Remember to include information which relates to concepts, connections between facts or similar information over which you are seeking a declaration of CCI. This type of information may not be present in a document accompanying the application. For example, you may be

willing to reveal that you are intending to increase stress tolerance in GM plants, but you may ask for a declaration of CCI over the fact that you are intending to combine more than one stress tolerance gene into one GM plant.

Precisely describe the sensitive information in each document and identify each occurrence of the sensitive information in each document.

Question A3: In each document listed in A1, where exactly does the information occur for which you are seeking a declaration of CCI?

In a copy for each document listed in A1, mark up each occurrence of the information for which you are seeking a declaration of CCI. It is very important that you do this thoroughly. Also, mark up each occurrence of previously declared CCI, if applicable.

Applicants often brightly highlight the information over which they seek a declaration of CCI. Highlighting clearly visualises what information you would like to keep confidential. It makes it easier to clearly recognise the information and avoid inadvertent disclosure of your commercially sensitive information.

For example, details of a gene or gene construct may be mentioned on numerous occasions and in different parts of one or more documents (see examples to Question A2). You must identify and mark up each mention of the gene construct as part of this application.

Question A3.1. For each document listed in A1, have you attached a copy in which all CCI was marked?

Attach a marked-up copy of each document listed in A1 to this application. Ensure that title, date and author of each document match those listed in A1.

☐Yes ☐No

If No, provide details.

Enter your statement of reasons.

Question A4: For each document listed in A1, have you supplied a copy from which you have removed all CCI?

The Regulator is required to disclose information in certain circumstances. For example, the Regulator is required to provide copies of DIR licence applications, if requested, to members of the public, and in response to requests under Freedom of Information legislation.

To help the Regulator protect the information for which you are seeking a declaration of CCI, you need to provide a copy of each document listed in A1, with all the information specified as CCI removed. A copy **not** containing sensitive information is referred to as an expurgated copy.

When removing sensitive information, you will have to add alternate text that replaces the removed sensitive information, and ensure that the copy without sensitive information makes sense when it is read in isolation.

For example, if you are seeking to have the name of a gene declared as CCI (but not the name of the trait it provides), you should provide the Regulator with an expurgated copy of the relevant document with all occurrences of the gene name deleted. In place of the gene name, you might want to use generic words such as 'the insect resistance gene' to ensure readability.

For each document, you need to:

- ensure you have removed all information as listed in A2 and marked up in A3, over which you are seeking a declaration of CCI (cross-check for consistency)
- clearly title this copy of each document '*Expurgated copy of [add title, author and date of document]* and
- ensure you list the exact title of each document in the Signatures and consent to release documents section at the end of this application form before signing.

If your GM plant were transformed with *gene x* from tomato, and the gene and source organism are described in detail in journal article *Gene X* by AUTHOR C, 2005. If you are seeking a declaration of CCI regarding the fact that you are using *gene x* from tomato in your experiments, you would seek CCI over **reference** to the journal article (rather than over the **content** of the journal article itself). In this case, there is no document which could replace the document containing the CCI and your answer to this question would be No. However, you are still required to provide expurgated copies of any documents, in which CCI occurs.

☐Yes ☐No

If No, provide your reasons below.

Enter your statement of reasons.

Question A5: Have you previously applied for this information to be declared CCI?

☐Yes ☐No

If Yes, provide details of the previous application.

Enter details of previous applications for declaration of CCI which have not yet been declared or have been refused.

Section 2, Part B: Justification for treatment of information as CCI

For information to be declared CCI you must satisfy the Regulator that the information you have specified in Section 2, Part A is:

1. a trade secret; or

2. any other information that has a commercial or other value that would be, or could be reasonably expected to be, destroyed or diminished if the information were disclosed; or

3. other information that concerns the lawful commercial or financial affairs of a person, organisation or undertaking and, if it were disclosed, could unreasonably affect the person, organisation or undertaking.

In the appropriate spaces below, give your reasons why the information identified in Section 2, Part A, satisfies one or more of the above criteria. Ensure that all the reasons provided relate to the current situation at the time of lodgement of this application for declaration.

It is in your interests to ensure that you provide adequate justification to support your claim for a CCI application.

Question B1: **Is the information a trade secret?**

☐Yes ☐No

If Yes, use the spaces below to address the following questions as well as any other issues you consider relevant to your application.
If No, move on to Question B2.

Question B1.1. Is the information known outside your business?

☐Yes ☐No

If Yes, state by whom it is known, indicate if this entity is engaged in the same business as yourself and why you believe the information is nevertheless a trade secret. If you have conducted literature searches to support this claim, provide details.

If No, how do you know it is not known outside your business? If you have conducted literature searches, provide comprehensive details of the searches undertaken, e.g. databases searched, parameters of the search etc. If you have not conducted searches, indicate why not and explain why you are confident that the information is not known outside your business.

Enter your statement of reasons.

Question B1.2. Does the information have value to you and/or your competitors?

☐Yes ☐No

If Yes, provide comprehensive reasons. Note that the Regulator may request evidence to support your claims.

Enter your statement of reasons.

Question B1.3. Does the information provide you with an advantage over your competitors?

☐Yes ☐No

If Yes, identify your competitors and describe how the information gives you an advantage over them.

Enter your statement of reasons.

Question B1.4. Have you taken any measures to guard the secrecy of the information?

☐Yes ☐No

If Yes, describe the measures taken and evidence of them, e.g. confidentiality agreements, contract clauses etc.

Enter your statement of reasons.

Question B1.5. Have you spent significant effort or money in developing the information?

☐Yes ☐No

If Yes, provide indicators of time and money spent on developments undertaken, and attach any available evidence.

Enter your statement of reasons.

Question B1.6. Would it be easy for others to acquire or duplicate the information irrespective of its disclosure by the Regulator?

☐Yes ☐No

If Yes, why is the information nevertheless a trade secret?

If No, why not?

Enter your statement of reasons.

Question B1.7. Is your information used or useable in an identifiable trade?

☐Yes ☐No

If Yes, what trade?

Enter trade and your statement of reasons as to why it could be used.

Question B1.8. Provide any further relevant statements in support of your claim that the information is a trade secret. Attach available evidence, or other material.

Enter your statement of reasons and attach evidence or other material.

Question B2: Is the information other information that has a commercial or other value that would be, or could be reasonably expected to be destroyed or diminished if the information were disclosed?

☐Yes ☐No

If Yes, use the spaces below to address the following questions as well as any other issues you consider relevant to your application.

If No, move on to question B3.

Question B2.1. Why is the information of value to your business?

What evidence do you have to support that assessment? If you are relying in whole or in part on literature searches, then provide comprehensive details of searches undertaken, e.g. databases searched, parameters of the search etc.

Enter your evidence and/or other details.

Question B2.2. Provide estimates of the value of the information to your business and a justification for that estimate.

Enter your estimates and justification for the estimate.

Question B2.3. Would the information have a monetary value to an arms-length buyer?

☐Yes ☐No

If Yes, why would it have value? Who would be interested in buying the information? If possible, give an approximate estimate of the value and give reasons for that estimate.

Enter your statement of reasons.

Question B2.4. Would you expect the value of the information to be diminished or destroyed if disclosed?

☐Yes ☐No

If Yes, provide real and substantial grounds for this conclusion. Include evidence, if available.

Enter your statement of reasons and include evidence.

Question B2.5. Is the information the subject of a confidentiality agreement with another party?

☐Yes ☐No

If Yes, provide details and evidence.

Enter the details of the confidentiality agreement and supporting evidence.

Question B2.6. Is the information currently the subject of a patent application or an existing patent?

☐Yes ☐No

If Yes, at what stage of the patent process is your application? Describe how the information covered in the patent or patent application relates to the information over which a declaration is sought. When did you make the application? If the material has already been released or will be released as part of that process, why would its release by the Regulator concern you? Provide evidence of your patent application. If an existing patent, provide the number(s) and countries.

If No, is the information likely to be the subject of a patent application? State when you expect the application to be made. Explain why you have so far not made a patent application.

Enter your explanation and provide evidence as necessary.

Question B2.7. In the space below provide any further relevant statements in support of your claim that the information that has a commercial or other value that would be, or could reasonably be expected to be destroyed or diminished if the information were disclosed.

Attach available evidence, or other material.

Enter your statement of reasons.

Question B3: Is the information other information that concerns the lawful commercial or financial affairs of a person, organisation or undertaking and if it were disclosed, could unreasonably affect the person, organisation or undertaking?

☐Yes ☐No

If Yes, use the spaces below to address the following questions as well as any other issues you consider relevant to your application.

If No, move on to the Declaration and consent to the release of documents (Section 3).

Question B3.1. How would disclosure adversely affect your organisation?

Provide details. For example, if you would anticipate adverse effects on the organisation's business, then identify those effects and provide a reasoned justification. If possible attach any available evidence.

Enter your statement of reasons.

Question B3.2. Why would disclosure be unreasonable?

Enter your statement of reasons.

Question B3.3. In the space below provide any further relevant statements in support of your claim that the information concerns the lawful commercial or financial affairs of a person, organisation or undertaking which, if disclosed, could unreasonably affect the person, organisation or undertaking.

Attach available evidence, or other relevant material.

Enter your statement of reasons.

Section 2, Part C: Additional information if application for declaration is related to field trial locations

You must complete this Part **only** if you wish to have information about locations at which field trials involving GMOs are occurring, or are proposed to occur, declared to be CCI.

The Regulator **must refuse to declare** information about locations at which field trials involving GMOs are occurring, or are proposed to occur, **unless satisfied** that disclosure of the location would be likely to result in:

a) significant damage to the health and safety of people; or

b) significant damage to the environment; or

c) significant damage to property.

Provide detailed answers to the questions below and attach evidence where appropriate. Inadequate answers will require the Regulator to seek clarification and could delay the processing of your CCI application or of an application to which this application for CCI applies, or the Regulator may not consider, or cease to consider, a DIR licence application which is accompanied by this form.

Question C1: If this information is disclosed, would it be likely to result in significant damage to the health and safety of people?

☐Yes ☐No

If Yes, provide details such as how the disclosure would be likely to result in damage and why this damage would be significant. Where possible, provide evidence to support your statements.

Provide details and evidence.

Question C2: If this information is disclosed, would it be likely to result in significant damage to the environment?

☐Yes ☐No

If Yes, provide details such as how the disclosure would be likely to result in damage and why this damage would be significant. Where possible, provide evidence to support your statements.

Provide details and evidence.

Question C3: If this information is disclosed, would it be likely to result in significant damage to property?

☐Yes ☐No

If Yes, provide details as to how the disclosure would be likely to result in damage and why this damage would be significant. Where possible, provide evidence to support your statements.

Provide details and evidence.

Question C4: Is there any other information you wish to add in respect of Part C?

☐Yes ☐No

If Yes, provide details.

Enter your statement of reasons.

Section 2, Part D: Details of any prejudice that would be caused to a person by disclosure of the information

The Regulator may refuse to declare that information is CCI, if the Regulator is satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person.

In the space provided, please provide additional information about the extent to which prejudice to any person would be caused as a result of disclosure of the information, including any prejudice which may result to the applicant and your reason for making that claim.

Provide additional information regarding any prejudice.

Section 3: Signatures and consent to the release of documents

This declaration and consent must be completed and signed by a person with the authority to sign on behalf of the organisation.

I declare that:

- I am duly authorised to sign this declaration
- the information supplied on this this application and attachments (if any) is true and correct at this time and
- I am aware that the making of a false or misleading statement may be punishable by imprisonment or a fine under the *Gene Technology Act 2000* and corresponding state law.

☐Yes ☐No

I hereby give my consent to the disclosure by the Office of the Gene Technology Regulator (OGTR) of the documents and all information contained in the documents titled:

Enter details, such as title, author and date, of the expurgated copies of the documents attached under A4.

☐Yes ☐No

I understand that the Gene Technology Regulator may provide the documents listed above, and any other document as applicable, to a person making a request under section 54 of the *Gene Technology Act 2000* in relation to a DIR licence application.

☐Yes ☐No or not applicable

I confirm that I have taken measures to ensure that these documents do not contain any information which is Confidential Commercial Information (CCI), being information which has been previously declared CCI or which is awaiting assessment as the subject of a declaration for CCI.

☐Yes ☐No

I agree that this consent authorises the disclosure by the OGTR of any such information and shall not hold the Commonwealth or its agents and employees in any way liable for any damage that may be incurred by any person or organisation as a consequence of its disclosure in the event that one or more of the documents contain CCI, being information which has been previously declared CCI or which is awaiting assessment as the subject of a declaration for CCI.

☐Yes ☐No

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

If signing on behalf of an organisation, please also complete the following declaration.

I declare that I am duly authorised to sign this consent on behalf of	Enter organisation name
Print name:	Print name
Signature:	……
Job title:	Enter job title
Date:	Select date