

Application for Declaration

that specified information is confidential commercial information (CCI)

Information for completing the CCI form

This document contains:

- general information about the form and associated documents ('CCI Form Guidance'), and
- information for individual sections and specific questions within those sections.

Please note that additional guidance is only provided for a subset of questions in the application form. Links to this additional information are also provided in relevant places in the CCI application form.

A [CCI form Examples](#) document is also available.

CCI Form Guidance

How this application works

The information you supply in the CCI application form will be used to inform the Gene Technology Regulator's (the Regulator's) decision on whether to declare information as CCI.

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, as directed by the CCI Form, you must indicate that declared CCI is present, provide a reference number for the declared CCI and indicate which documents contain the information.

Any documents sent with the form and identified as containing information claimed as CCI will be treated as CCI while the application for declaration of CCI is being processed.

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 in the form that there is additional information attached, noting the attachment title/number and the page number(s).

If the CCI status of previously declared CCI has changed and the information no longer meets the criteria for CCI, you should notify the Regulator and request to have the CCI revoked.

What is CCI?

To assess an application for dealing with genetically modified organisms (GMOs), the Regulator requires information about the GMO and the proposed work. Some of this information may be information that an applicant may wish to keep confidential. The applicant can ask the Regulator to protect this information by declaring it as CCI. However, the information must meet certain statutory criteria in order for it to be declared CCI. These criteria are explained in this document and in the CCI form. Please see our [CCI page](#) for more information about CCI.

You need to tell us exactly what information you want to protect from disclosure. It is your responsibility to clearly indicate confidential information. Failure to do so could result in release of the information. You must also tell us how the information meets the requirements for protection from disclosure under the *Gene Technology Act 2000* (the Act).

Using the CCI application Form

In this form you need to clearly identify and describe the information for which you are seeking a declaration of CCI.

For each piece of information, you will need to:

- clearly specify the information – describe each piece of information for which you are seeking declaration as CCI;
- provide evidence to justify why each piece of information meets the criteria for declaration as CCI;
- identify any documents that contain the information and detail where the information is found in the documents;
- provide titles of any documents containing the specified information;
- for information in DIR application documents, also provide a copy of each identified document from which all CCI has been removed (including previously-declared CCI).

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.

Associated Applications

Where applicable, this 'Application for Declaration that specified information is CCI' should be submitted at the same time as the information that you wish to be protected e.g. with a DIR or DNIR licence application, applications for Accreditation, or Notifiable Low Risk Dealings (NLRD). If an application for CCI is not submitted, the information **will not be protected under the Act**.

Any document containing information which is claimed to be CCI, **MUST** be clearly marked to indicate that it contains information to be treated as 'Sensitive'

The information for which you are seeking a declaration of CCI must meet criteria set out in s185(1) of the Act. This is provided in the relevant sections of the form. It is recommended that you ***seek your own legal advice*** to determine whether the specified information meets these criteria before completing this form.

If you are unsure whether certain information that you may need to protect will be required to assess an associated licence application, please discuss with the OGTR before sending it.

Timeframe for a decision on a declaration of CCI

While there is no statutory timeframe for a decision on the declaration of specified information as CCI, the OGTR will make every effort to provide a decision within a reasonable timeframe.

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

Section 2 Information in support of the application

General information for this Section

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 **specified information**, not to specified text in a particular document. Once declared, the specified information will be treated as 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 identifying which parts of text in any document, would disclose the information. In short, you need to clearly describe the information we need to keep secret and where to find it.

Section 2, Part A 'Information in relation to which a declaration is sought' requires that you identify the specified information and any previously declared CCI that is relevant to the documents you are submitting.

Please note that personal information has protections under the *Privacy Act 1988* and the *Freedom of Information Act 1982*. The OGTR does not disclose personal information to a third party or the public unless required by law. If you have questions about protection of personal information, please refer to our [Privacy Page](#) on the OGTR website or contact the OGTR before completing your *application for declaration of CCI*.

Section 2, Part B 'Justification for treatment of information as CCI' requires that you provide a justification for your request that information be declared CCI. You must satisfy the Regulator that each piece of 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 'Additional information if application for declaration is related to field trial locations' Additional information is required if your application relates to field trials. Please contact the OGTR to discuss this if you wish to seek declaration of field trial site locations as CCI.

Section 2, Part D 'Public Interest information' allows you to provide details of any information relevant to disclosure in the public interest, including any prejudice that disclosure would cause.

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.

Information for Specific Questions

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

2A 1 Please specify from either your DIR or DNIR application or other document, the exact information for which you are seeking a declaration of CCI.

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

In your answer:

- Be specific about the information for which you are applying for a declaration of CCI – the Act only permits specified information to be declared CCI.
- List each piece of information for which a declaration of CCI is sought.

The Regulator cannot make a decision on whether to declare that the information is CCI unless the information is clearly specified.

If you are seeking declaration for a number of pieces of information, it would be helpful to provide a short title e.g. 'gene abc' for the information that can be referred to in later parts of the form.

See the [CCI form Examples](#) document

2A 2 Have you previously applied for some or all of this information to be declared CCI by the OGTR?

If you answer yes to this question, provide details:

- The CCI declaration identifier (e.g. CCI-DIR-XXX-X) for any related information already declared CCI, or CCI for which you have applied.
 - If all the information for which you are currently seeking a declaration of CCI - as identified in question A1 - is exactly the same as that in an existing CCI declaration, you do not need to apply again i.e. you should not complete a new CCI application. However, you should indicate on any DIR or DNIR application form or any other document, that there is current CCI included in those documents. If your current CCI relates to a DIR application, you will also need to provide an expurgated copy of your DIR application documents from which all declared CCI has been removed. See guidance for question 2A 4 for information on expurgated documents. See also the DIR and DNIR application forms, available on the OGTR website on the [Apply for GMO approval](#) page.
 - If some of the information for which you are currently seeking a declaration of CCI - as identified in question 2A 1 - has previously been declared CCI, please identify the information previously declared, including the CCI identifier.
 - If any previous applications for the same information are currently under consideration, please include the CCI identifier.
- If any information in a previous CCI declaration, is present in the documents supplied in a current licence/certification/accreditation application, and no longer meets the criteria for declaration as CCI (if, for example if it is now in the public domain):
 - Provide the CCI identifier.
 - Identify which specific information no longer meets the criteria for CCI (this may be all of it or some).
 - Request revocation of CCI for any such information separately in writing – contact the OGTR for information.

- This information will continue to be treated as CCI until it has been revoked and any review rights for revocation are exhausted.

2A 3 For each piece of information listed in 2A 1 and 2A 2, please provide the location of the information within the specified document(s).

For each piece of specified information:

- list all documents that disclose the information, including the title, date (and author, if appropriate) for each document
- identify/list exactly where the specified information is disclosed within each document
- include information identified in question 2A 2 as current CCI, or information that you listed as under consideration as CCI, if it is present in any of the documents you are submitting
- you could provide this answer as text or in a table, whichever is clearer.

It is not acceptable to identify the specified information for which a declaration is sought by referring only to an entire document, or indeed an entire table or block of text in a document, if some of the information in the document, table or block of text is not sought as CCI.

Note: Provision of this information is to assist OGTR staff in identifying documents that may require protection. However, the location of the information within documents does not form part of your description of the specified information for which you are seeking a declaration. The precise details of the specified information that you are seeking to be declared CCI must be included in your answer to 2A 1.

2A 4 Is your specified information related to a DIR application?

This question relates to whether the information for which you are seeking declaration as CCI was submitted as part of an application for a DIR licence. If the information for which you are seeking declaration as CCI is related to a DIR application, you must complete question 2A 5 and provide expurgated documents. If your application for declaration of CCI relates to an application for a DNIR licence or another type of documents, you do not need to supply expurgated documents and can proceed to Part B.

The Regulator is required to provide copies of DIR licence applications, if requested, to members of the public under section 54 of The Act. This includes any documents submitted as an attachment to that application, not just the application form.

2A 5 Provision of documents from which all requested CCI has been removed.

If your specified information is related to a DIR application, then for each document identified in 2A 3, you are required to supply an expurgated copy from which you have removed all requested or previously declared CCI. If you are unable to provide an expurgated copy please explain why.

You must provide a copy of each document identified in 2A 3, with all the information specified as CCI removed, or you will need to provide reasons for not doing so (see below). A copy not containing the specified information is referred to as an expurgated copy. This will be released to the public on request.

In table 2A 5, enter the title of each expurgated document you are supplying i.e. each document listed in 2A 3, for which you can provide an expurgated copy.

Ensure the documents are titled in the following format: 'Expurgated copy of [original title].'

For each document for which you are supplying an expurgated version:

- ensure that you have removed all relevant information namely:
 - specified information identified in 2A 1 over which you are seeking a new declaration of CCI

- specified information identified in 2A 2 which has been previously declared as CCI (and not revoked)
- specified information identified in 2A 2 that is currently under consideration for declaration as CCI
- ensure you have removed only the specified information, not whole tables or paragraphs which also contain other information

When removing the specified information, you would ideally ensure that the expurgated copy makes sense when it is read in isolation. For instance, you may add alternate text that replaces the removed information. Cross-check documents for consistency. See [CCI form Examples](#) document for more information.

If you are unable to provide an expurgated copy of any documents listed in 2A 3, you need to list those documents and provide a reason why you are unable to do so. See [CCI form Examples](#) document for information about situations where you may not be able to provide an expurgated copy of a document.

If you have some documents for which expurgated copies can be supplied and others for which expurgated copies cannot be supplied, you will need to provide the relevant information in both parts of this question.

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

General information

See relevant information for s185(1) of the Act, provided on the form.

In answering the appropriate questions related to Trade secret (2B 1 and subsequent questions) of Commercial or other value (2B 2 and subsequent questions,) or Other information (2B 3 and subsequent questions), give your reasons why the information identified in Section 2, Part A, satisfies one or more of the above statutory criteria. Different pieces of information for which you are seeking declaration that the information is CCI, may meet different criteria. Thus, for each piece of information, you should consider which criteria it satisfies and include answers to the questions in 2B 1, 2B 2 or 2B 3 as appropriate.

It is in your interest to ensure that you provide adequate justification to support your claim for a CCI declaration. There are accepted legal principles and tests to establish whether information meets the criteria in s185 of the Act.

Note that the Regulator may request further evidence to support your claims.

If information has been publicly disclosed, it is unlikely to meet the criteria to be declared CCI. Consider all places where you may have disclosed information including publications, patents, media releases, quarterly and annual investor reports, and reports filed with and made available by other Australian or international regulators.

You should seek your own legal advice in relation to the information required to establish your claims that the specified information is CCI.

For each section, the form provides guidance about what information you need to provide to answer the question and indicates where further information is needed depending on whether you answer Yes or No to a particular question.

Information for Specific Questions

Information that is a trade secret – s185(1)(a)

2B 1 Is any of the information a trade secret?

If you answer Yes to B1, you will need to fill in the following table and answer all subsequent questions (2B 1.1 to 2B 1.10) in this section as guided by the form.

In the table provided, list any of the information identified in question A1, for which you are seeking declaration as CCI on the basis that it is a trade secret. If you have other information that does not fit this criteria, do not include it here. It will be captured in other sections.

Please list any piece(s) of information as detailed in answer to 2A 1, for which you are seeking declaration as CCI on the basis that it is a trade secret.

2B 1.2 Is the information available in the public domain?

2B 1.2.2 Have you conducted searches to determine whether the information for which you are seeking CCI is available in the public domain?

If you answer Yes to 2B 1.2.2 please provide information about searches undertaken. This may include (but is not limited to) general internet searches, searches for specific types of documents such as journal articles, annual reports, documents from other regulators or patents or searches of technical databases. Provide comprehensive details of searches undertaken, e.g. databases searched, parameters of the search etc. This will assist us in understanding whether the information is publicly available.

2B 1.3 Is the information known outside your organisation?

If Yes, how is the information protected as a trade secret outside your organisation?

The answer to this question will assist us in understanding the extent to which the specified information is known outside your organisation or the steps that are taken to protect the information if it is disclosed outside your organisation. For example, any agreements or other arrangements you have with persons outside your organisation who know the information, that protects its value as a trade secret.

2B 1.4 Have you taken any measures to guard the secrecy of the information?

If Yes, describe the measures taken.

This may include (but is not limited to) confidentiality agreements, contract clauses, limited dissemination of the information within or outside your organisation, etc.

2B 1.9 Would it be easy for others to acquire or duplicate the information?

If it would be easy to acquire or duplicate, the information may not be considered a trade secret. If you answer 'Yes' for this question you will need to justify how the information could be regarded as a trade Secret.

Question B1.10 Provide any further relevant statements in support of your claim that the information is a trade secret, attaching any relevant information.

This question provides a space where you can include any other information relevant to support your claim, any information that was not supplied in answer to one of the previous questions in this section. You do not need to answer this question if you have already provided all the information that you wish to by answering the previous questions.

Information of commercial or other value - s185(1)(b)

Questions in this section seek to establish that the specified information has commercial or other value to you or another person/organisation and that the commercial or other value of the information would be, or could reasonably be expected to be, destroyed or diminished if it were disclosed.

If you are unsure of the kind of information encompassed by this provision you should **seek your own legal advice**.

2B 2 Does any of the information have commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed?

You may answer Yes to either Commercial value, or to Other value, or you may answer Yes to both. If you answer No to both, proceed to Question B3.

In the table provided, list any information identified in question 2A 1, for which you are seeking declaration as CCI on the basis that it has commercial or other value. Identify whether it has commercial value, other value or both, by indicating Yes in either or both of the right-hand columns as appropriate. If you have other information that does not fit this criteria, do not include it here. It will be captured in other sections.

The form indicates which subsequent questions you must answer in this section, depending on whether you are claiming Commercial Value, Other value or both:

- If you are claiming Commercial value only you must answer Questions 2B 2.1 – 2B 2.5 and 2B 2.7 including any sub-questions. You may also choose to answer 2B 2.8.
- If you are claiming Other value only, you must answer Questions 2B 2.1 – 2B 2.4 and 2B 2.6 - 2B 2.7 including any sub-questions. You may also choose to answer 2B 2.8.
- If you are claiming both Commercial value and Other value, you must answer 2B 2.1 – 2B 2.7 including any sub-questions. You may also choose to answer 2B 2.8.

2B 2.1 Is the information available in the public domain?

As this part of the Act is concerned with the effect of disclosure on the value of the information, it is unlikely that that it could be protected as CCI if the information is already in the public domain.

2B 2.1.2 Have you conducted searches to determine whether the information for which you are seeking CCI is available in the public domain?

If you answer Yes to this question please provide information about searches undertaken. This may include (but is not limited to) general internet searches, searches for specific types of documents such as journal articles, annual reports, documents from other regulators or patents or searches of technical databases. Provide comprehensive details of searches undertaken, e.g. databases searched, parameters of the search etc.

2B 2.2 Is the information known outside your organisation?

If you answer Yes, please list any measures in place to protect the value of the information if it is known outside your organisation. For instance, you may have contractual or other arrangements that limit the disclosure of the information.

2B 2.3 Have you taken any measures to guard the secrecy of the information?

If you answer yes, please list any measures in place to guard the secrecy of the information. This may include (but is not limited to) confidentiality agreements, contract clauses, limited dissemination of the information within your organisation.

2B 2.4 Is the information currently the subject of a patent application or an existing patent?

If an existing patent, provide the number(s) and countries.

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 patent application?

If the material has already been released or will be released as part of that process, why would its release by the Regulator destroy or diminish its commercial or other value?

If a patent application related to this information has not yet been made, but is likely to be, state when you expect the application to be made.

2B 2.5 Please provide any information you have about the monetary value of the specified information to an arms-length buyer.

Please provide information about why it would have monetary value. Include information about who would be interested in buying the information, give an estimate of the value and give the reasons for that estimate.

2B 2.6 If the value to your organisation is not commercial value, please indicate what the other value of the information is to your organisation and how that value might be diminished or destroyed if disclosed.

Please provide information about what type of value the information has to you - for example reputational value - and how that value would be destroyed or diminished by disclosure of the information.

Other business information – s185(1)(c)

2B 3 If the information is not a trade secret (as set out in question 2B 1) or commercially or otherwise valuable information (as set out in question 2B 2):

Does the information concern the lawful commercial or financial affairs of a person, organisation or undertaking?

And, would disclosure of the information unreasonably affect the person, organisation or undertaking?

If you answer Yes to 2B 3, you will need to answer all subsequent questions in this section as guided by the form.

If you are unsure of the kind of information encompassed by this provision, you should **seek your own legal advice**.

In the table provided, list the information identified in question 2A 1, for which you are seeking declaration as CCI on the basis that it concerns lawful commercial or financial affairs. Information that does not fit this criteria should not be included here. It will be captured in other sections.

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

See relevant information for s185(2A) of the Act, provided on the form.

2C 1 Are you seeking to claim CCI for a field trial location?

If you answer Yes to 2C 1, you will need to answer 2C 1.1 – 2C 1.3 and you may choose to answer question 2C 1.4.

If No, proceed to Section 2 Part D.

In general, information about field trial locations where dealings with GMOs are occurring will be required to be disclosed under sections 54 and 138, unless the Regulator is satisfied that disclosure would involve significant risks to health and safety. If you are seeking declaration of CCI for field trial locations, please contact the OGTR to discuss prior to submitting your application.

Part 3 Signatures and Consent

Section 3 Signatures and consent to the release of documents

If the answer to any of these questions is No, the OGTR may not be able to process this application, so in that case, you must contact the office to discuss prior to completing and submitting the form.

If your application for declaration that specified information be declared CCI does not relate to information for a DIR licence application, please proceed to the signatures section and complete the form by signing.

If your application for declaration that specified information be declared CCI relates to information for a DIR licence application, please complete the following before signing.

I declare that:

- I am the applicant, or duly authorised by the natural person or organisation making this application, to sign this declaration; and
- the information supplied in 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* or a corresponding state law.

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

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 I have listed at Table 2A 5:

If your application for declaration of CCI relates to information supplied as part of a DIR licence application, you must ensure that each expurgated document listed in answer to Question 2A 5 (Table 2A 5) is also listed here. If you have indicated in 2A 5 that you can supply an expurgated version of any document(s) your answer here would be Yes. You must ensure that you provide the same title as provided in answer to 2A 5. A simple way to do this might be to copy Table 2A 5 into this space.

If your answer to Question 2A 5 was No for some documents, you would not consent to releasing them here as there is no expurgated version.

Answers to the remaining statements in this section relate to your consent to release the expurgated document(s) only, as identified in Table 2A 5 and listed above. These relate to:

- understanding about the release of the expurgated the documents as required by the Act
- the measures you have taken to ensure they do not contain any CCI, and
- understanding of your responsibilities to ensure the expurgated documents do not contain CCI

Signatures

The signatures section must be completed either with an electronic signature, or physically signed and scanned for submission.