

Application for Declaration

that specified information is confidential commercial information
(CCI)

Examples for the CCI form

A [CCI form Information](#) document is also available and general information on CCI is available on the [OGTR website](#).

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

Please note that only questions for which examples are available are included in this document. Links are provided in the CCI application form.

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.

1. For individual pieces of information:

- Names of genes, promoters/terminators/other genetic elements/primers e.g. “*Gene Abc32*”, “*Promoter Xyz98*” or “*nos terminator*”.

This will protect the name of the genes, promoters/terminators/other genetic elements, or primers. Protecting just the name will not protect other information such as the source of the gene, the gene family to which it belongs, or the trait expressed, or whether a promoter is a constitutive or tissue specific promoter, its source, or expression patterns.
- Gene sequence e.g. “sequence of *Gene Def65*”.

This will protect the gene sequence but will not protect other information such as the name of the gene or any other information related to the gene.
- Source organism for genes or other genetic elements e.g. “the source of *Gene Ghi54*, the Golden hamster”.

Protecting the source will not protect any other information such as the name of the gene or genetic elements.
- Construct details – information about the elements in the construct, order and size of the construct.
Example (1) “Details of *Construct 28562*, specifically the names and sources of individual elements in the construct, the order of elements in the construct and the construct size.”
This will protect all specified information which may be contained in text, a table or a figure.
Example (2) “The sequence and order of elements of *Construct 28562*”.
This will protect the way the elements of the construct are arranged in the construct but would not protect the names of the genetic elements of the construct such as the genes of interest, marker genes or promoters or the sources of the genetic elements.
- Gene function, including protein name e.g. “The fact that *Gene Abc32* encodes a reductase enzyme named *Reductase Abc32*.”

If the gene name provides information about the specific enzyme, then CCI declaration would need to be sought for the gene name.
- *Phenotype* e.g. “The fact that *Gene Klm76* produces plants with drought tolerant phenotypes is sought as CCI, however the resulting phenotype may be generally described as abiotic stress tolerant.”

This will protect the specific details of the phenotype, but allow a broad description as being one of a group of phenotypes without identifying the details.
- Identity of recipient variety or cell line for transformation.

This will protect the name of the variety or line used as the recipient for transformation, but not the species.

➤ Manufacturing steps

This will protect specific steps in a manufacturing process but not the general method or cell lines used in the manufacturing process of the GMO.

2. Connections between individual pieces of information

Information for which you are seeking a declaration of CCI that relates to connections between facts or similar information. This type of information may or may not be stated explicitly in the documents accompanying the application.

- “The identities of genes *Abc34*, *Def 68* and *Ghi29* including names, sources, function and phenotype may be used. The fact that two or more of these genes may be combined in a single GM line and the details of the constructs used to produce the drought tolerant phenotype is requested as CCI.”
- This will protect the fact that individual genes may be combined in specific GMOs, as well as the details of the constructs used which could reveal this information. It would not protect details of the individual genes or the overall phenotype of the GMOs.

3. References that provide a link to information that is sought as, or already declared as, CCI:

References containing information that would lead to identification of information over which you were seeking CCI. For a reference to be declared as CCI, it would have to provide a link to specific information being sought as CCI in a way that would allow anyone with reasonable knowledge of the subject area to discover the CCI information itself. The CCI declaration would only protect the disclosure of the reference in any context that would enable the discovery of the specified information.

- e.g. “The paper ‘Gene x influence on trait y in tomato’ by Author C, 2005 provides information about gene x. A declaration of CCI is being requested for the identity of Gene x in relation to our application DIR XXX. Mention of this paper in connection with the application would provide a direct link to the identity of the gene. Thus, the reference to this paper in relation to the application is sought as CCI.”
- This will protect direct reference to the journal article that provides a link to the information for which you are seeking CCI declaration. It would not protect the content of the journal article itself.
- A patent describing the characteristics of the GMO and its method of administration may be available but the link between this patent and a licence application could be claimed as commercial in confidence. This may be relevant if the link between the patent and the licence application provides information, such as the stage of development of a GM therapy, or specific details of GMO constructs, that provide commercial value for the applicant which would be lost if revealed.

4. Groups of documents for which the value is the compilation, rather than individual facts:

Trial protocols - particularly for clinical trials - where individual methods or other details of the trial are compiled into a single protocol (may be a single document or a collection of documents) for conducting the trial. Individual pieces of information may be unremarkable in isolation, for example a specific method in the protocol may be common practice, but the whole protocol is of value due to the time, effort and experience in gathering these individual pieces into a single protocol.

In this case, you might seek a declaration of CCI for the collection of documents but not for individual facts contained in the document.

- “The collection of *Documents A, B, C, D and E*, which in combination form “*Clinical trial 5 Protocol*” is sought as CCI.”

If there are also specific pieces of information within those documents which are otherwise novel and commercially confidential, declaration of CCI would need to be sought for that specific information, separately, as in Example 1.

- “The collection of *Documents A, B, C, D and E*, which in combination form the “*Clinical trial 5 Protocol*” is sought as CCI, and

➤ “The names and sequences of primers for detection of *gene Rst87* are sought as CCI.”

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

For each piece of information list each document, and where in that document, the information appears. See also the [CCI form Information document](#) (p5).

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.

Identify each piece of specified information you are referencing.

Be specific about where exactly in the document the information is listed.

For example:

The name of *Gene Abc32* is disclosed in the following documents:

“DIR XXX application form” submitted to the Regulator on XX Month 20XX:

- Page 10, Part 9.2, paragraph 1

Attachment 2 to DIR XXX application form, entitled “Details of genetic modifications”:

- Page 2, Table 1, line 4, column 3
- Page 6, Figure 3, gene name in construct figure and figure legend.

This detail must be provided for each piece of specified information for which declaration of CCI was requested.

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

The Regulator is required to provide copies of [DIR](#) licence applications, if requested, to members of the public under section 54 of the *Gene Technology Act 2000* (The Act). This includes any documents submitted as an attachment to that application, not just the application form.

If your application for declaration of CCI is related to a DIR application, you must either supply expurgated documents for any documents identified in 2A 3, or provide a reason why an expurgated version cannot be supplied.

See the [CCI form Information](#) (p5) document for more.

Document titles must be clearly linked to the original document and titled as indicated in the question. For example:

If the original document containing the specified information is “Application for DIR XXX” the expurgated document should be titled “Expurgated copy of Application for DIR XXX”.

If the information is in more than one document you must provide an expurgated copy of each document, as identified in your answer to 2A 3, titled as indicated above.

You must submit the expurgated document with this application.

When removing sensitive information, you would ideally ensure that the expurgated copy makes sense when it is read in isolation.

For example, you may add alternate text that replaces the sensitive information: if you are seeking to have the name of a gene declared as CCI, you should provide the Regulator with an expurgated copy of the relevant document where all occurrences of the gene name replaced by generic text such as ‘the insect resistance gene’ or ‘Gene x’ to ensure readability.

If you cannot expurgate parts of your document in a way that ensures your expurgated copy makes sense, indicate in the document that some information that you consider to be commercially confidential has been removed e.g 'CCI removed' or 'confidential information removed'.

In some cases, providing an expurgated copy of a document may not be possible. For example:

➤ If you are seeking a declaration of CCI over reference to a journal article (see example for 2A 1) that provides a direct link to the specified information, there is no document that can replace the journal article. However, you are still required to provide expurgated copies of any other documents in which CCI occurs, including expurgating the details of the journal article as cited in the text of your application document(s) and in any reference list.

➤ If you are seeking CCI over a collection of documents for which the value is the compilation, rather than individual facts (see example for 2A 1), you would need to state in answer to this question that this is the reason you are seeking CCI and that there are no expurgated documents as it is the collection that is of value. You will also need to identify exactly which documents are included in the compilation.

"The collection of documents "*Clinical trial 5 protocol*" is sought as CCI. The documents in this protocol are:

Document A (Authors 1, 2 &3, published 2016): "*Detection methods for gene Rst87*"

Document B: "*Recruitment of trial participants*"

It is the collection of these documents as an overall trial protocol that is of value. Thus, no expurgated copies of documents have been provided."

➤ If you are also seeking a declaration of CCI over specified information contained in the compilation of documents, you should indicate this. If declaration of CCI for the collection of documents was granted, entire documents would be protected, thus expurgated copies would not be supplied. However, if the specified information is also contained in other documents which do not form part of this compilation, you would need to provide expurgated copies of those documents.

In such cases, it could be helpful to supply a copy of any documents containing CCI, where specified information is highlighted.