



OGTR Newsletter

Issue #5: Confidential Commercial Information (2 of 2 newsletters)
 Date: 25 March 2019

OGTR News and Announcements

- The Health Department team involved in the 3rd Review of the National Gene Technology Scheme received a Highly Commended award in the category of Building Strong Relationships at Health’s Australia Day awards. OGTR staff were recognised for their part in working collaboratively with the Health Department team, including providing technical input and responding to requests for information about the operation of the gene technology regulatory scheme.
- Registrations are now closed for the 8th OGTR National Institutional Biosafety Committee (IBC) Forum being held on 28-29 March 2019. The OGTR looks forward to engaging with accredited organisations and their IBCs on topics relevant to the regulation of genetically modified organisms in Australia.
- The [new application form](#) for GMO licence variations was issued in January 2019. Variation applications via email will not be accepted after 31 March 2019.
- Notification for trial of GM vaccines against Ross River virus infection in horses ([DIR 167](#)).
- Call for comment on RARMP for field trial of GM chickpea ([DIR 166](#)). Photo: Eitan Ferman (via [Wikipedia](#))
- A new [chickpea biology document](#) is also available, which provides an overview of baseline biology information relevant to risk assessment of genetically modified forms of the species.



Chickpea pods

Confidential Commercial Information (CCI) – in practice

This is the second of two newsletters about CCI. The first outlined the basics of CCI ([Issue 4](#)). This newsletter will provide more details around applying for information to be declared as CCI.

To apply for information to be declared as CCI you need to fill out the [CCI application form](#) and have it signed by someone who has authority to sign on behalf of your organisation. The Regulator will decide if the information meets the criteria to be declared as CCI and will advise you accordingly. There is no statutory timeframe for this process. However, incomplete, inconsistent or ambiguous CCI applications associated with DIR licence applications can interfere with our ability to perform statutory consultations so can impact on DIR decision timeframes. If we don’t know what we can release then we can’t consult with the public on a RARMP so may have to ‘stop the clock’.

It is important that information to be declared as CCI is described accurately and unambiguously. We have strict protocols around handling of CCI and want to ensure that we are protecting the right information.

Useful links or special points of interest:

- [Link to CCI Fact Sheet](#)
- [CCI application form](#)

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Pre-submission

- **Does the OGTR need the information?** Sometimes an applicant supplies information that is not required for the assessment. It is always best to check if confidential information is needed before supplying it.
- **Has it already been declared as CCI for a previous related application?** CCI protection lasts forever, unless revoked, so does not need to be re-declared. Conversely, OGTR cannot release CCI unless it has been revoked or you have expressly agreed to its release.

CCI application

- **Does it meet the criteria to be declared as CCI?** Newsletter 1 described the basis on which information can be declared as CCI. If it does not meet at least one of these criteria it cannot be CCI under the *Gene Technology Act 2000*.
- **Have you described what information is requested as CCI clearly and unambiguously?**
- **If the CCI is associated with a DIR licence application, have you provided an expurgated copy of the DIR application form?** Legally, any DIR application form, excluding CCI, must be provided to a person who requests it.
- **Has only CCI information been removed from the expurgated copy of the DIR application form?** e.g. in a table only the CCI information should be removed, not the whole table.
- **Have you checked the CCI application and the expurgated DIR application for consistency between what is removed and what is described as CCI?** Be careful with citing references that might reveal CCI.

Submission

- **Have you submitted your CCI through a secure method?** Your information is valuable. Remember to use a secure channel to submit it to us, not regular email (see newsletter 1 for details).

Post-declaration

- **Does the information still meet the criteria for declaration as CCI?** If you have subsequently published the information or been granted a patent then the information may no longer meet the criteria to be CCI. Please keep us informed when the status of information changes and the CCI declaration should be revoked.

Examples of Suitable/Inadequate CCI applications

Suppose you need to protect the identity of the *OsCAD* gene in your DIR application.

CCI application form	✗	We would like all information about <i>CAD</i> genes in rice to be CCI.
	✓	We would like to protect as CCI: <ul style="list-style-type: none"> • Name of <i>OsCAD</i> • Reference Jasmine et al 2009 which would lead to disclosure of name of <i>OsCAD</i>
CCI redaction in supporting documents	✗	Gene A from rice is known to be involved in a pathway for lignin formation. <i>OsCAD</i> was sequenced in 2009 (Jasmine et al 2009), and has similarity with other CAD genes.
	✓	Gene A from rice is known to be involved in a pathway for lignin formation. Gene A was sequenced in 2009 (Reference A), and has similarity with other [CCI] genes.

