



OGTR Newsletter

Issue #4: Confidential Commercial Information (1 of 2 newsletters)
Date: 17 December 2018

OGTR News and Announcements

- Updates on the two Gene Technology Reviews are as follows:
 - [The Third Review of the National Gene Technology Scheme](#) – this was a broad-reaching policy review undertaken for the Legislative and Governance Forum on Gene Technology (the Forum), independently of the Gene Technology Regulator (the Regulator). The Final Report is now available on the review website.
 - [The Technical Review of the Gene Technology Regulations](#) – The Forum is considering amendments to the Gene Technology Regulations 2001 proposed by the Regulator. The amendments are substantially the same as those put forward for public consultation on 30 November 2017. Should the amendments be agreed by the Forum and then made by the Governor-General, OGTR would notify regulated stakeholders with details of the amendments and commencement dates.
- **Reminder:** All applications submitted via email must be sent to ogtr.applications@health.gov.au. This ensures that your application can be received, acknowledged and processed without delay.
- The 8th OGTR National Institutional Biosafety Committee (IBC) Forum is to be held on 28-29 March 2019. This forum will provide an opportunity for representatives of accredited organisations and their IBCs to engage with the OGTR on topics relevant to the regulation of genetically modified organisms in Australia.
- The Regulatory Science Network (RSN) annual symposium was held in Canberra in November 2018. The theme was risk communication. A number of OGTR staff attended and Dr Peter Thygesen, the OGTR Chief Regulatory Scientist spoke on the difference between hazard and risk.
- DIR updates: Notification of application for field trial of GM wheat ([DIR 165](#))
Notification of application for field trial of GM Chickpea ([DIR 166](#))



Dr Peter Thygesen at the RSN

Confidential Commercial Information (CCI)

This is the first of two newsletters about CCI. The first outlines the basics of CCI.

The second will provide more details around applying for CCI. In order for the

Regulator to assess some licence applications, applicants may be required to provide information which they want to keep secret or confidential. Applicants can apply to have this information declared as CCI.

The Regulator may declare Information CCI if:

- it is a trade secret; or
- it has a commercial or other value that may be compromised if the information were disclosed; or
- it concerns lawful commercial or financial affairs that could be unreasonably affected if the information were disclosed.

What would not usually be classified as CCI? The Regulator may refuse to declare information as CCI if it does not meet one of the three criteria above, when the public interest in releasing the information outweighs any likely loss to the person or organisation requesting the CCI declaration, or in most cases, the location of field trials.

Organisations or applicants wishing to apply for a CCI declaration should seek their own independent legal advice.

Useful links or special points of interest:

[Link to CCI Fact Sheet](#)

[Link to PSPF](#)

[Link to ABR - AusKey](#)

[Link to RSN information on OGTR Website](#)

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If you have any suggestions or questions, please email us at ogtr@health.gov.au

Phone (Free-call): 1800 181 030





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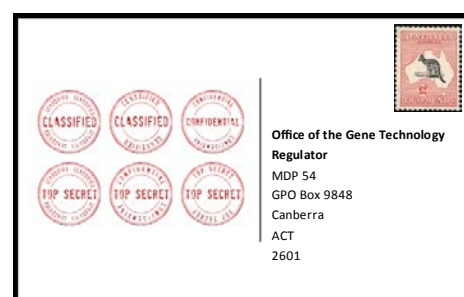
Who has access to CCI? Access to CCI is limited to those OGTR staff that need to use or access the information to perform their duties and, where necessary, advisory committees and government agencies consulted during the decision making process. Staff must ensure the declared CCI is properly protected from disclosure during storage or for any required transmission of CCI.

How do I apply to have information declared as CCI?

To apply to have information declared as CCI the appropriate CCI application form will need to be submitted. More detail will be provided in the next CCI Newsletter.

Transmission of CCI – To ensure your information is protected, any application documents or correspondence that contains CCI should be transmitted through secure channels.

- Ordinary unclassified email is not a secure channel.
- The OGTR’s preferred method for the secure transmission of CCI is the Australian Government’s Health Data Portal.
- The application could also be submitted on a USB via Express Post.

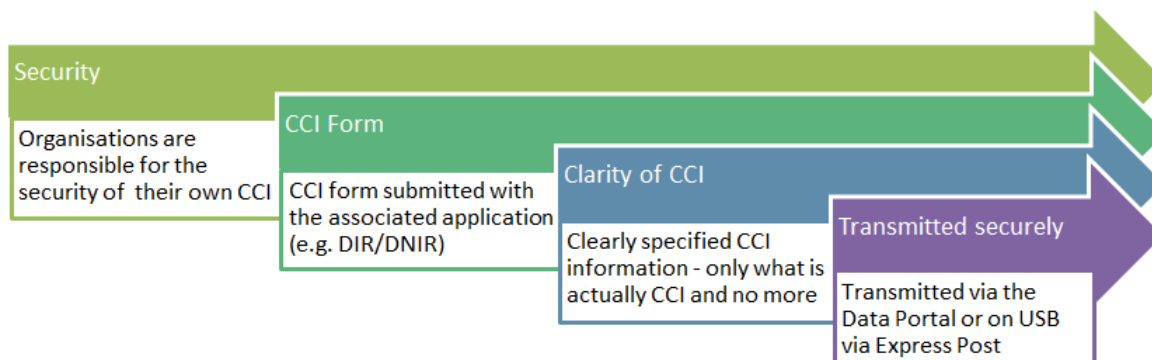


Secure transmission of CCI?

The Health Data Portal and AUSKeys

- Use of the Data Portal requires an individualised AUSKey. An AUSKey is a secure login that identifies individual users when they use various government online services on behalf of a business. AUSKeys are issued by the Australian Business Register (ABR).
- An AUSkey administrator is usually already established within an organisation to manage individual user’s AUSKeys for use in various other government online services. The organisation’s AUSkey administrator is usually in the Finance or IT area of a business.
- Once the AUSkey administrator is located, they can assign an individual AUSkey and the new user can register their AUSkey through the ABR. Registration and access to the Data Portal is then relatively straight forward.
- To seek further assistance with establishing access to the Data Portal contact ogtr.applications@health.gov.au.

CCI applications – the following figure outlines the essentials when considering submitting a CCI application



Next issue

- Impacts/Consequences/Advice and Specificity issues with CCI
- Correctly classifying information as CCI
- Advice from the OGTR to organisations and IBCs submitting documents containing CCI

