USE AND DISCLOSURE OF INFORMATION

National Gene Technology Scheme
An Australian, State and Territory Governments Collaboration

Use and Disclosure of Information

Regulatory schemes have some protections in place for commercial information and data provided in confidence for the purposes of gaining an approval or authorisation.

Applicants wishing to protect their Confidential Commercial Information (CCI) are currently required to request a declaration from the Gene Technology Regulator (the Regulator) that the information provided is CCI.

This is a second application made to the Office of the Gene Technology Regulator (OGTR), in addition to the application for a licence.

Handling CCI applications and confirmation of CCI by OGTR staff leads to delays in processing licence applications and can delay consultation processes.

The Scheme requires a high degree of transparency. Although the Regulator's decisions must be transparent, commercially valuable data and information must be protected to maintain confidence in the regulatory processes and the Scheme.

Information declared as CCI has no end date and is treated as CCI forever, leading to long-term disclosure and handling risks to the Regulator.

Want more detail?

You can review the proposed changes to use and disclosure of information in the draft Gene Technology Amendment Bill.

What changes are proposed?

To streamline licence applications, the CCI declaration process is proposed to be removed.

The definition of CCI is proposed to change, and handling and use of CCI would have similarities to how information is handled under existing Freedom of Information legislation.

This approach is different to other regulatory schemes that have data protection and data exclusivity periods. However, those outcomes would still be achieved.

What does this mean?

When a licence application is made to the OGTR, and consultation on a Risk Assessment and Risk Management Plan (RARMP) is proposed, the Regulator will seek confirmation from applicants about whether any information in the RARMP is CCI and should not be disclosed.

The applicant will be requested to respond by a specified date, providing timeframe certainty and removing unnecessary delays. The Regulator will then decide whether information is CCI at that point in time and so cannot be disclosed.

Any data and information that is provided to the Regulator will still be protected as Regulator Information and can only be used and disclosed for specific purposes prescribed in the Act.

Contact us for more information on this consultation:
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