

The Record of GMOs and GM Product Dealings

What is the Record of GMOs and GM Product Dealings?

The Record of GMO and GM Product Dealings (the Record) is a complete list of:

- (a) all dealings with genetically modified organisms (GMOs) approved by the Gene Technology Regulator (the Regulator); and
- (b) all dealings with genetically modified (GM) products approved by other relevant product regulators (listed below).

The purpose of the Record is to provide the Australian public with ready access to information about all GMOs and GM products being used in Australia.

Australia is, we understand, the first country in the world to make such a comprehensive Record available to the general community. This Record is a substantive demonstration of the openness and transparency underpinning Australia's new regulatory system for GMOs, which commenced operation on 21 June 2001.

What sort of GMOs and GM products will be listed on the Record?

The Record contains information about:

- Notifiable Low Risk Dealings (NLRDs) notified to the Regulator.

NLRDs are dealings with GMOs that have been assessed over time as posing low risks, provided that certain risk management conditions are met (See Part 6, Division 2 of the *Gene Technology Act 2000*.) For example, NLRDs must be:

- conducted within a facility certified by the Regulator to be at least Physical Containment (PC) Level 2;
- appropriately supervised by a Biosafety Committee established within an Organisation accredited by the Regulator; and
- if transported, transported in accordance with the Regulator's *Guidelines for the Transport of GMOs*.

- All licences granted by the Regulator.

The Record includes information about licences for both GMOs approved for intentional release into the Australian environment, as well as those only licensed for dealings within a contained facility. (See Part 5 of the *Gene Technology Act 2000*.)

- Any GMO included on the GMO Register.

The purpose of the GMO Register is to enable certain dealings with GMOs to be undertaken without the requirement for a licence to be held by a named individual or organisation. For a dealing to be placed on the GMO Register, the Regulator would have to be satisfied that the dealing is sufficiently safe that it can be undertaken by anyone, and that safety does not depend on oversight by a licence holder. This could only be after the particular dealing had been licensed for a period of time. Currently, no GMO has been approved for inclusion on the GMO Register. (See Part 6, Division 3 of the *Gene Technology Act 2000*.)

- GM products approved by other relevant regulators.

The regulatory agencies which must include their approvals of GM products on the Record of GMO and GM Product Dealings are:

- the National Registration Authority for Agricultural and Veterinary Chemicals (for GM products approved for use as agricultural and veterinary chemicals);
- the Therapeutic Goods Administration (for GM products approved as therapeutics);
- the National Industrial Chemicals Notification and Assessment Scheme (for GM products approved as industrial chemicals); and
- the Australia New Zealand Food Authority (for GM products used in foods for human consumption).

Although these GM products are approved by government agencies other than the Regulator, including such GM product approvals on the Regulator's Record ensures that the Australian community can easily access a comprehensive Record of all GMOs and GM products. (See Part 9, Division 6 of the *Gene Technology Act 2000*.)

Where does information included on the Record come from?

Information contained in the Record relating to GMO approvals is based on information provided to the Regulator by the organisations/individuals approved to undertake certain dealings with the GMOs. Organisations which supply this information have been asked to carefully check the information included on the Record. The information is also checked by the Office of the Gene Technology Regulator.

Information included on the Record relating to GM Product approvals is provided to the Regulator by the relevant product regulators listed above. Should you want further information about the GM products referenced in the Record, you should approach the relevant product regulator directly.

Is the Record included in the OGTR's Website the final, complete Record?

The *Gene Technology Act 2000* (section 138(8)) provides that the Regulator must ensure that information to be included on the Record be entered on the Record as soon as reasonably practicable. In keeping with this commitment to introduce an open and transparent system as soon as possible, the OGTR has developed word-based documents to make information available through its website at the earliest possible opportunity.

Every effort has been made to include as much information about all dealings approved under the previous voluntary system, which was in effect prior to 21 June 2001. The Regulator does, however, need to ensure that processes set out in the *Gene Technology Act 2000*, such as those relating to commercial-in-confidence information, are carefully observed. The Record will, therefore, be continuously added to as regulatory processes are completed.

Similarly, every effort has been made to ensure the accuracy of the Record details. However, if errors are identified, proponents are asked to notify the Regulator so that corrections can be made.

The Office of the Gene Technology Regulator (OGTR) is now working closely with IT specialists, Dialog, to develop a system called the Gene Technology Information Management System (GTIMS). This system will include a more sophisticated version of the Record, which will make it easier for you to search for the information in which you are interested. A separate factsheet on GTIMS is available. That version of the Record is expected to be completed by the end of 2001, and in operation at the beginning of 2002.

Confidential commercial information

When you view the contents of the Record, you may find the term 'commercial-in-confidence' entered in some places. This is because section 184 of the *Gene Technology Act 2000* provides that a person may apply to the Regulator for a declaration that specified information is confidential commercial information (CCI) for the purposes of the *Gene Technology Act 2000*. For example:

- applicants for a licence may apply for parts of their application to be treated as CCI;
- applicants for certification or accreditation may apply for parts of their applications to be treated as CCI;
- people providing information to the Regulator as part of a notification of a NLRD may apply for parts of their notification to be treated as CCI; or
- people making submissions to the Regulator may seek a declaration that parts of their submissions are CCI.

Where the Record uses the Term 'Application for confidential commercial information', you will know that an application has been made to the Regulator for

information to be treated as CCI. Once the Regulator has made a decision on an application for CCI, the Record will be updated to either:

- include the information, if the application for CCI is refused by the Regulator; or
- to include the term 'confidential commercial information' where the Regulator decides to protect the information.

Without pre-empting any decision taken by the Regulator in relation to an individual application, the Act is premised on the release of as much information about dealings with GMOs as possible, including in relation to the location of field trial sites.

Response to feedback

The Record of GMOs and GM Products has undergone a range of improvements since its release on 21 June 2001, in response to the public's feedback. The Record now includes more comprehensive information, trial sites listed in Local Government areas, and coloured maps of every state and territory with field trials marked in the correct geographic areas.

The OGTR welcomes any feedback about how the Record can be further improved.

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