

**Office of the Gene Technology Regulator**

THERAPEUTIC GOODS ADMINISTRATION

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THIS POLICY IS EFFECTIVE FOR A PERIOD OF 12 MONTHS COMMENCING 1 JULY 2003.  
THIS POLICY WILL BE REVIEWED AFTER 30 JUNE 2004.

## NEW POLICY ON STORAGE OF GENETICALLY MODIFIED ORGANISMS

### Background

Experiments involving Genetically Modified Organisms (GMOs) have been undertaken in Australia for more than 25 years. The Genetic Manipulation Advisory Committee (GMAC) and its predecessors provided guidance for the conduct of this work.

Following completion of experiments, GMOs were often stored in refrigerators and other facilities. Storage was often desirable in order to verify or repeat experiments or to conduct further studies based on the earlier research. Many research and academic organisations have diligently catalogued, labelled and stored GMOs, but some records may be incomplete.

Although the risks posed by storage of GMOs may be negligible, the potential risks to human health and safety and the environment associated with their removal from storage, use and disposal fall within the responsibilities of the *Gene Technology Act 2000*.

### Legislative Requirements

Risks posed by storage of GMOs are addressed in the *Gene Technology Act 2000*. The Act regulates GMOs that were stored before the Act commenced, as well as GMOs that have been stored since the Act commenced on 21 June 2001. The Act seeks to promote the safe and proper storage of all GMOs by prohibiting storage unless storage is authorised, and by imposing penalties if GMOs are not stored appropriately.

Under the Act, unauthorised storage of GMOs is an offence and the offence provisions apply regardless of whether the GMOs are stored safely. It is an offence to possess and store GMOs for the purposes of conducting future research or experiments involving the GMOs unless storing the GMOs is authorised.<sup>1</sup>

Storage of GMOs is authorised (ie. it is *not* an offence to store a GMO) if it is:

- undertaken pursuant to a GMO licence;
- a notifiable low risk dealing (NLRD) and the person has completed the steps necessary to perform the NLRD<sup>2</sup>;
- an exempt dealing; or
- part of a dealing listed on the GMO Register.

<sup>1</sup> See sections 10, 32 and 33 of the *Gene Technology Act 2000* and corresponding State law.

<sup>2</sup> Regulation 13 of the Gene Technology Regulations sets out the process that a person must complete before an NLRD can be lawfully conducted.

## **Amnesty arrangements**

Following suggestions from a number of organisations and individuals, and in recognition of the effort which may be required to identify, record and appropriately re-store GMOs, the Regulator has agreed to an amnesty on unauthorised storage until **30 June 2004** provided that GMOs are stored 'safely'.

'Safe storage' means that all of the following are demonstrated:

1. *All the GMOs are stored in sealed containers; AND*
2. *All the sealed containers holding the GMOs are labelled in a way that enables details about the GMOs to be identified; AND*
3. *All the GMOs are stored inside a facility that is currently certified by the OGTR to a minimum of PC2 level, OR*  
*All the GMOs are stored in a cold storage cabinet that maintains temperatures inside the cabinet below 0° Celsius which is either:*
  - (a) Lockable; or*
  - (b) Located in a secure area that prevents access to the cabinet from persons not responsible for its contents.*

Persons who store GMOs safely under the amnesty but without other authorisation should still obtain proper authorisations during the amnesty period.

If the storage of GMOs is not authorised and the GMOs are not stored safely, the GMOs should be destroyed in accordance with the *Guidelines for the Certification of Facilities*.

Any questions on this policy should be directed to the Contained Dealings Section of the OGTR via email to [ogtr@health.gov.au](mailto:ogtr@health.gov.au) or by telephone on 1800 181 030.

Authorisation Stamp

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