



INFORMATION FOR INSTITUTIONAL BIOSAFETY COMMITTEES ON CHANGES TO GENE TECHNOLOGY REGULATION

Why have the changes occurred ?

The amended Regulations which commenced on **31 March 2007** were initiated by the Gene Technology Regulator with extensive input from the scientific community. Amendments to the *Gene Technology Act 2000* and consequential changes to the *Gene Technology Regulations 2001* (which come into effect on **1 July 2007**) result from recommendations made by the independent statutory review which was accepted by Commonwealth, State and Territory governments in 2006 and introduced to Federal Parliament in 2007. More information on this process is available at www.ogtr.gov.au/regsreview/resamend.html

As part of an ongoing process of review the Regulator has also issued revised certification, accreditation and transport guidelines. Together, these changes offer more streamlined processes for lower risk dealings and more transparent processes for other identified activities.

What are the major changes that affect IBCs ?

- [More host/vector systems classified as 'exempt' from 31 March](#)
- ['Exempt' dealings have no specified level of containment from 1 July 2007](#)
- [List of 'exempt' dealings no longer need to be supplied to the Regulator from 1 July](#)
- [Dealings with GM rats, mice and specified viral vectors must be conducted as NLRDs in certified PC1 facilities from 1 July](#)
- [Reclassification of some DNIRs¹ to NLRDs² from 31 March](#)
- [NLRDs listing to be maintained and notified to the Regulator in annual report from 1 July](#)
- [DIR³ licence applications either limited & controlled release \(with 150 day consideration\) or general release \(255 day consideration\) from 1 July](#)
- [DNIR & DIR licence variation requests must be decided within 90 days from 1 July](#)
- [Revised PC2 Certification guidelines from 1 July](#)
- [New accreditation guidelines, application form & instruments from 1 July](#)
- [Revised transport guidelines from 1 July](#)

Where can I obtain more information ?

Information sessions for IBCs were held in capital cities in late May and early June 2007 and separate information sheets have been prepared for exempt dealings, NLRDs and DIRs. Copies of these information sheets can be obtained from the OGTR website at <http://www.ogtr.gov.au/ibc/index.htm>, the new legislation and regulations from www.ogtr.gov.au/pubform/legislation.htm and revised forms from www.ogtr.gov.au/pubform/forms.htm.

More information about the changes can be obtained from the Office of the Gene Technology Regulator website at www.ogtr.gov.au, by email to ogtr@health.gov.au or by telephoning 1800 181 030

¹ Dealings *not* involving Intentional Release (DNIRs)

² Notifications of Low Risk Dealings (NLRDs)

³ Dealings involving the intentional release of GMO into the environment (DIR)