



CHANGES TO EXEMPT DEALINGS

What sort of containment do exempt dealings require ?

From **1 July 2007** the only legislative requirement for exempt dealings is that they do not involve the intentional release of GMOs into the environment.

From July 1 2007 exempt dealings do not require a specified level of containment. However, guidance on the appropriate containment for exempt dealings may be found on the OGTR website at www.ogtr.gov.au/pdf/certification/ExemptDealGuide.pdf.

What sort of reporting is required for exempt dealings ?

From **1 July 2007** there are no requirements to report to the Gene Technology Regulator on exempt dealings.

Some previously Exempt dealings are now Notifiable Low Risk Dealings (NLRDs)

Following removal of containment requirements for exempt dealings from **1 July 2007**, a small number of previously Exempt dealings are now classified as 'PC1 NLRDs' to maintain containment and regulatory oversight.

From **1 July 2007**, the following dealings must be conducted as NLRDs in facilities certified to PC1 (or above)¹ and of the appropriate design for the dealing type:

- (a) a dealing involving a genetically modified laboratory mouse or a genetically modified laboratory rat, unless:
 - (i) an advantage is conferred on the animal by the genetic modification; or
 - (ii) because of the genetic modification, the animal is capable of secreting or producing an infectious agent;
- (b) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 (*i.e. in vitro dealings with non-viral vectors or defective viral vectors unable to transduce human cells*) if the donor nucleic acid confers an oncogenic modification;
- (c) a dealing involving a defective viral vector able to transduce human cells in a host mentioned in item 4 of Part 2 of Schedule 2 (*animal or human cell culture*), unless:
 - (i) the vector is a retroviral vector; or
 - (ii) the donor nucleic acid confers an oncogenic modification.

[Part 1, Schedule 3 Gene Technology Regulations 2001 as amended 2007]

If you commenced work on such a dealing as an exempt dealing you need to obtain approval from your IBC for the NLRD.

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 All existing OGTR-certified facilities should already meet the necessary containment requirements for PC1 (or above) and therefore may continue to be used for these dealings.