



**Australian Government**  
**Department of Health and Ageing**  
**Office of the Gene Technology Regulator**

**Some implications of the *Gene Technology Amendment Regulations 2011*  
(commencement date 1 September 2011) for regulated organisations**

The Commonwealth Gene Technology Amendment Regulations 2011 (the Amendment Regulations 2011) will commence on 1 September 2011. The Amendment Regulations 2011 introduce changes to the Commonwealth Gene Technology Regulations 2001 (the Regulations), which will affect the way some dealings with genetically modified organisms (GMOs) are classified and the requirements in relation to certain types of dealings from 1 September 2011.

**Transitional Provisions**

The Amendment Regulations 2011 will provide for a transitional period to enable organisations to identify any **current** dealings that may require a higher level of classification (eg exempt → Notifiable Low Risk Dealing (NLRD), or NLRD → a dealing not involving intentional release (DNIR)) and make notifications/applications to the Gene Technology Regulator (the Regulator). Such dealings may continue under their current classification for up to one year from commencement of the Amendment Regulations 2011. After this time, the dealings (including storage of the GMOs) must cease **unless** a new authorisation has been given before this one year transition period expires on 1 September 2012 [see regulation 4 of the Amendment Regulations 2011] ie an IBC assessment has been undertaken (for NLRDs) or a licence has been issued by the Regulator (for DNIRs).

Any new dealings with GMOs proposed on or after 1 September 2011 will be classified as scheduled in the Amendment Regulations 2011, ie no transitional provisions apply.

Organisations should undertake their own reviews of how dealings with GMOs should be classified in order to ensure ongoing compliance with the *Gene Technology Act 2000*. The OGTR can provide advice on possible reclassification of specific exempt dealings, NLRDs or DNIRs, if requested.

**Notifiable Low Risk Dealings (NLRDs) - Conduct and reporting**

**Change:** regulations 13, 13A, 13B and 13C introduce new requirements for the conduct of NLRDs and the assessment and recording of NLRDs by IBCs.

The amended regulation 13 specifies requirements for NLRDs. This includes compliance with the new *Guidelines for the Transport, Storage and Disposal of GMOs* which is required for NLRDs as of 1 September 2011. The amended regulation 13A introduces a 5 year time limit to the authority to conduct a dealing as an NLRD, including transport, storage and disposal of the relevant GMOs. There are transitional end dates for existing NLRDs. The new regulation 13B details the requirements for IBCs in assessing NLRD proposals, including providing a record of assessment. The new regulation 13C details the requirements for keeping of records and provision of information to the Regulator by persons or accredited organisations conducting NLRDs.

These changes were developed to clarify the roles and responsibilities of persons or organisations proposing and undertaking NLRDs and of IBCs.

Additionally, some containment requirements have been either clarified or changed. These include: dealings involving GM laboratory strains of rabbits and guinea pigs can be conducted in PC1 facilities, and NLRDs involving GM Risk Group 3 microorganisms must be conducted in at least PC3 facilities (see below).

## **Changes to classification of dealings**

### ***Reclassification of some NLRDs as exempt dealings***

**Change:** the list of exempt dealings at Schedule 2, Part 1 of the Regulations has been amended, and the list of host/vector systems for exempt dealings at Schedule 2, Part 2 has been expanded.

As a result, some dealings currently classified as NLRDs will be classified as exempt after commencement of the Amendment Regulations 2011. Note that exempt dealings must not involve intentional release into the environment and the document *Guidance Notes for Containment of Exempt Dealings* (available on the OGTR website) can be used to assist with the undertaking of these dealings. New proposals (on or after 1 September 2011) will automatically be classified as exempt and any relevant requirements apply.

Some specific changes include the amended Item 3A, Schedule 2, Part 1, which provides for dealings with animals in which somatic cells have been modified *in vivo* to be classified as exempt, but only if the vector is not able to be remobilised from the somatic cells after the free viral vector is cleared from the animal. Additionally, the classification of exempt dealings has been altered to include the cloning and expression of oncogenes in exempt host/vector systems in certain situations. The culture volume allowed for exempt dealings has also increased.

While no immediate action is required in relation to continuation of current dealings, it would assist the OGTR to know which NLRDs are no longer being conducted. Information on NLRDs which have ceased will be sought in your organisation's annual report to the Regulator, commencing from the 2011-2012 reporting year.

### ***Reclassification of some exempt dealings as NLRDs/DNIRs***

**Change:** dealings involving host/vector systems able to transduce human cells will not be classified as exempt.

This means dealings with avipox vectors will no longer be exempt and will be regulated in the same way as for other viral vectors able to transduce human cells, ie as NLRDs or DNIRs depending on the characteristics of the inserted nucleic acid.

For any existing exempt dealings requiring an NLRD or licence on 1 September 2011, the transitional provisions apply. New proposals (on or after 1 September 2011) will automatically be required to be assessed as NLRDs or licensed and any relevant requirements apply before these dealings can commence.

### ***Reclassification of some DNIRs as NLRDs***

**Change:** Schedule 3, Parts 2 and 3 of the Regulations, which specifies what kinds of dealings are, and are not, NLRDs have been amended.

This means that some dealings which are currently licensed as DNIRs will be classified as NLRDs after commencement of the Amendment Regulations 2011. Such dealings can continue to be conducted under the relevant licence, in accordance with any licence conditions. Alternatively, they can be notified to the Regulator, once they have been assessed by the relevant IBC as a (new) NLRD. Once assessed (as required by 13B(a)), the dealings can be conducted in accordance with the requirements for NLRDs, and the licence surrendered (with the consent of the Regulator).

A notification of a NLRD previously covered by a licence should include all information specified in the new regulation 13C. This information should be submitted in the annual report in the same way as required for all other NLRDs.

New proposals (on or after 1 September 2011) will automatically be required to be assessed as NLRDs and any relevant requirements apply.

The OGTR will endeavour to identify current DNIRs which may fall into this category, in order to assist organisations. However, organisations are responsible for making their own reviews. If a licence exists for a dealing that may be a NLRD under the amendments, please contact the OGTR to ensure correct classification. Further information may be required to confirm the classification.

### ***Reclassification of some NLRDs as DNIRs***

**Change:** Schedule 3, Part 3, which specifies dealings that are not NLRDs, has been amended.

This means that it is possible that a small number of current NLRDs will be classified as licensable (i.e. DNIRs) after commencement of the Amendment Regulations 2011. These relate to dealings with GM Risk Group 4 microorganisms, if they are not already licensed (see below), and some dealings involving avipox vectors. For any current NLRD requiring a licence, the transitional provisions apply. New proposals (on or after 1 September 2011) will automatically be classified as a DNIR and a DNIR application must be submitted to the Regulator and a licence issued before work can commence. Licence application forms are available on the OGTR website.

### ***Classification of viral vectors***

**Change:** classification of some viral vectors has been amended.

This results in the classification and regulatory requirements for some dealings with viral vectors increasing, while others will decrease. Guidance documents to assist with the classification of dealings with viral vectors (as of the 1 September 2011) will soon be available on the OGTR website. However, the Amendment Regulations 2011 should be read to ensure compliance when working with viral vectors.

### ***Dealings with GM Risk Group 3 (RG3) and Risk Group 4 (RG4) microorganisms***

**Change:** Schedule 3, Part 2.2 requires that NLRDs involving GM RG3 microorganisms be undertaken in facilities certified by the Regulator to at least PC3 level containment and that are appropriate for the proposed dealing, or in a facility approved in writing by the Regulator.

As this amendment does not involve an increase in the level of classification, the transitional provisions do not apply, and therefore compliance with the new containment requirements is necessary at the time the Amendment Regulations 2011 commence (ie 1 September 2011). The Regulator should be contacted with any questions about containment requirements for GM RG3 microorganisms.

**Change:** Schedule 3, Part 3 requires dealings involving GM RG4 microorganisms to be licensed.

In cases where an existing NLRD requires a licence, the transitional provisions apply to allow time for an application for a licence to be prepared and assessed.

These amendments will ensure that dealings with GM RG3 or RG4 microorganisms are consistent with Australia/New Zealand standard AS/NZS 2243.3:2010 'Safety in laboratories – microbiological safety and containment'.

**Table 1 Examples of changes in classification/containment requirements**

GMO Dealing	Current Regulations	Amendment Regulations 2011
Animals with modified somatic cells ( <i>in vivo</i> by a replication defective viral vector)	NLRD	Exempt
Cloning and expression of oncogenes in exempt host/vector systems (in certain situations)	NLRD	Exempt
GM rabbits and guinea pigs	PC2 NLRD	PC1 NLRD
Culture volume for exempt dealings and NLRDs	Maximum 10 litres	Maximum 25 litres
Host/vector systems able to transduce human cells (ie avipox vectors)	Exempt NLRD	PC2 NLRD DNIR
Some replication defective retroviral vectors	DNIR	PC2 NLRD
Some replication defective non-retroviral vectors	PC1 NLRD	PC2 NLRD
NLRDs involving GM RG3 microorganisms	At least a PC2 NLRD	PC3 NLRD
Dealings with GM RG4 microorganisms	NLRD/DNIR	DNIR

Please note that the information provided in this document should be considered as general advice and does not constitute legal advice.

***If you have any questions please contact the OGTR*** on 1800 181 030 or [ogtr@health.gov.au](mailto:ogtr@health.gov.au).