



Questions and Answers

The Gene Technology Amendment Regulations 2011

What are the Gene Technology Amendment Regulations 2011?

The Gene Technology Amendment Regulations 2011 (the Amendment Regulations) will commence on **1 September 2011**. The Amendment Regulations introduce changes to the Gene Technology Regulations 2001 (the Regulations).

The Regulations support the operation of the *Gene Technology Act 2000* (the Act), providing technical details such as the requirements for undertaking laboratory-based work with genetically modified organisms (GMOs). The Regulations list specified GMO dealings as exempt dealings or notifiable low risk dealings (NLRDs), or as requiring licensing.

Why are the Regulations changing?

The changes ensure that the classification and regulation of dealings with GMOs remains commensurate with risk and up to date with current scientific understanding. This assists users to better understand and comply with their legislative obligations and supports the effective and efficient operation of the regulatory scheme for GMOs.

What is the scope of the changes?

The changes are technical in nature, primarily relating to conduct of contained GMO work such as laboratory research. They do not alter the policy settings of the GMO regulatory scheme. The substantive changes include: classification of GMO dealings as exempt dealings or NLRDs; classification of GMO dealings involving viral vectors; and the oversight and timeframes of NLRDs.

Do the changes relate to the environmental release of GMOs?

The changes do not relate to the requirements for environmental release of GMOs. The changes primarily relate to conduct of contained GMO work such as laboratory research.

How were the amendments developed?

The Gene Technology Regulator conducted a review in line with his functions under the Act. Proposals for amendment were developed based on feedback received from regulated stakeholders and experts, and on the operational experience of the Office of the Gene Technology Regulator (OGTR).

Was there consultation on the amendments?

Yes. Extensive consultation on the proposed amendments was conducted in May-June 2010 with the public, regulated organisations, the Gene Technology Technical Advisory Committee (GTTAC) and relevant government agencies and departments, including all States and

Territories. The Amendment Regulations were finalised, taking into account feedback received during the consultation.

Who approved the changes?

The Gene Technology Ministerial Council, which includes representation from States, Territories and the Commonwealth, approved the Amendment Regulations as required by the intergovernmental Gene Technology Agreement 2001. The Amendment Regulations 2011 were made by the Administrator of the Commonwealth of Australia on 2 June 2011.

Do the changes relax regulatory oversight for GMOs?

No. Some GMO dealings will now be subject to higher classification and requirements. The Amendment Regulations continue to require oversight of work with GMOs that is commensurate with risk. The requirements for conducting NLRDs have been updated to improve clarity of roles and responsibilities of organisations and institutional biosafety committees. Some GMO dealings are reclassified and will require lesser levels of authorisation, in line with current scientific understanding of risks. There are transitional provisions for GMO dealings already being undertaken and now subject to increased classification.

Are these changes to the Regulations related to the current review of the Gene Technology Act 2000?

No. The independent review of the Act has been initiated by the Gene Technology Ministerial Council and is not being undertaken by the Gene Technology Regulator or the OGTR. For further information about the review of the Act, contact GTMC.Secretariat@health.gov.au.

Where can I get a copy of the Amendment Regulations?

A copy of the Amendment Regulations and associated Explanatory Statement is available on the ComLaw website and can be assessed via the OGTR's website under 'What's new'.

If you have any questions please contact the OGTR on 1800 181 030 or ogtr@health.gov.au.