

TASMANIAN REGULATORY REQUIREMENTS:

CONTAINED RESEARCH AND GENETICALLY MODIFIED ORGANISMS

MAY 2009

All dealings in Australia involving genetically modified organisms (GMOs), including research in contained facilities (laboratories, glasshouses, animal houses, aquaria etc) are regulated under the national *Gene Technology Act 2001*. This legislation aims to protect the environment, and human health and safety. Dealings in contained facilities are classified as Dealings Not Involving Intentional Release (DNIRs), Notifiable Low Risk Dealings (NLRDs) or Exempt Dealings under the national scheme.

State and Territory Governments may also impose a second layer of regulation on dealings with GMOs, for marketing purposes. In Tasmania, the *Genetically Modified Organisms Control Act 2004* (GMO Control Act) underpins a moratorium on the release to the environment of viable GMOs which may impact upon the State's ability to position itself as one of few places in the world capable of producing GMO-free product. The moratorium covers plants, animals and micro-organisms, and includes open-air trialing. However, the policy allows GMO research in contained facilities, provided it has been approved by the national Gene Technology Regulator and subject to assessment of risk of escape in Tasmania.

Under the GMO Control Act, it is illegal to deal with GMOs in Tasmania without authorisation from the Tasmanian Government, even if the dealings are licensed or otherwise approved by the national Gene Technology Regulator. There are two exceptions:

- Dealings that are classified as exempt dealings under the national legislation.
- Dealings relating to human medical or pharmaceutical research or products.

The Tasmanian Government does not regulate these dealings under the GMO Control Act.

Taking into account these exceptions, the steps anyone planning research involving GMOs in a contained facility must undertake to avoid breaching the GMO Control Act are outlined overleaf. It is important to note that:

- Your Institutional Biosafety Committee (IBC) provides oversight to research involving GMOs. You must inform it of your plans before proceeding, including checking that the facilities you intend to use have a current, appropriate level of certification. This is generally PC 2 or greater.
- Other Tasmanian legislation may also apply. For example, if you wish to import a GMO that is a plant (including a seed, tuber or any other viable reproductive structure) from somewhere else in Australia, you must comply with requirements under the Tasmanian *Plant Quarantine Act 1997*.
- Other national legislation may also apply. For example, if you wish to import a GMO from outside Australia, you will need approval from the Australian Quarantine and

Inspection Service (AQIS). AQIS approval will not be granted unless the relevant approval from the national Gene Technology Regulator is also in place.

- Researchers seeking approval under the GMO Control Act should submit a full written account of the proposed dealings, including import, growth, analysis, disposal of waste or storage, where this will occur and for how long. The level of detail should be discussed with the person who will assess the application.
- The DPIW will endeavour to take not more than six weeks to assess an application. However, researchers should allow as much time as practically possible for the assessment process when scheduling their work.

For further information, please contact Biosecurity Policy Branch, Department of Primary Industries and Water, Tasmania on 6421 7630

