

## QUESTIONS & ANSWERS ON THE REVIEW OF THE GENE TECHNOLOGY REGULATIONS

**Australia's Gene Technology Regulator is reviewing the Gene Technology Regulations 2001 and is proposing that they be amended.**

### **What are Regulations?**

Acts of Parliament, such as the *Gene Technology Act 2000* (the Act), provide in law the Australian Government's approach to the regulation of any given activity. Regulations are the next tier of law. Sitting under the Act are the Gene Technology Regulations 2001. Importantly, Regulations have the same force of law as an Act of Parliament.

In general, Regulations provide the administrative, procedural and technical details which support the operation of an Act. For example, the Gene Technology Regulations 2001 (the Regulations) provide many technical details about the classification of, and requirements for dealing with, different genetically modified organisms (GMOs).

### **Why are the Regulations being reviewed?**

The aim of the review is to ensure that gene technology work is classified and regulated appropriately. It is also intended to clarify some definitions and resolve technical issues and inconsistencies in order to improve the efficiency of the regulatory system, and to assist users to better understand and comply with their legislative obligations.

### **How were the proposed amendments identified?**

The review has drawn on the experience of the Gene Technology Regulator (the Regulator) and the Office of the Gene Technology Regulator (OGTR) in administering the regulatory system, together with formal and informal feedback from stakeholder groups. This has included suggestions from the Gene Technology Technical Advisory Committee and various organisations that have to comply with the Regulations, in particular from their Institutional Biosafety Committees (IBCs), on areas of the Regulations that can be improved to bring greater clarity, efficiency and effectiveness to the regulatory framework.

### **What are the proposed amendments?**

The review process identified five key areas of for amendment:

- classification of dealings with GMOs as **exempt dealings**
- classification of dealings with GMOs as **Notifiable Low Risk Dealings** (NLRDs)
- classification of dealings with GMOs involving **viral vectors**
- **oversight of NLRDs**
- **timeframes** and other administrative matters.

The **Draft Gene Technology Amendment Regulations 2010** (the Draft Amendment Regulations) detail the proposed changes. All of the proposed amendments are technical or administrative in nature and none of them alter the risk management-based policy settings which underpin the regulatory system.

A consultation package has also been prepared to assist interested individuals and groups to understand the changes proposed in the Draft Amendment Regulations and participate in the consultation process. This package includes an overview paper, a discussion paper addressing each of the five areas of amendment, and an unofficial compilation of the proposed amendments with the current Regulations to allow the changes to be read in context.

### **How can I comment on the proposed changes to the Regulations?**

You are invited to submit your comments on the consultation version of the draft Amendment Regulations. The consultation documents are available on the OGTR website (<<http://www.ogtr.gov.au>> under “What’s New”) or via Freecall 1800 181 030. Your advice would be appreciated on whether the proposed changes to classification of certain dealings with GMOs are commensurate with any risks to the health and safety of people and the environment. Comments on other aspects of the amendments are also welcome.

Please note that the consultation period closes on **18 June 2010** and written submissions are required by that date.

### **What are the next steps in the review process?**

Matters raised in submissions will be taken into account in finalising the Amendment Regulations. The Regulator will then recommend to the Gene Technology Ministerial Council (GTMC) that the Regulations be amended. Following GTMC agreement, finalised Amendment Regulations will be submitted for consideration by the Executive Council and making by the Governor General. If agreed, it is anticipated that Amendment Regulations will come into force in early 2011.