

2011 Review of the *Gene Technology Act 2000* (GT Act)

Terms of Reference

In 2006, the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement* recommended that the Act be reviewed in five years to ensure that it continues to accommodate emerging trends (recommendation 8.1). In establishing this review, the Gene Technology Ministerial Council (the Ministerial Council) is aware of the Australian Government's position on biotechnology and the experience of the Gene Technology Regulator and his office in the operation of the *Gene Technology Act 2000 (Commonwealth)* (the Act) since the 2005-06 review.

The review will investigate:

- emerging trends and international developments in biotechnology and its regulation;
- the efficiency and effectiveness of the operation of the Act consistently across the national scheme for gene technology regulation in Australia; and
- the interface between the Act and other systems (e.g. other Acts and schemes).

Person/s undertaking the review are to advertise nationally, receive submissions from interested parties, and take into account overseas experience.

Background

The Act is the Australian Government's component of the nationally consistent regulatory scheme for gene technology in Australia. The object of the Act is to protect the health and safety of people and the environment from risks posed by, or as a result of, gene technology by identifying those risks and managing them by regulating certain dealings with genetically modified organisms (GMOs). The Act establishes a regulatory framework through which its object is to be achieved. This framework provides for a precautionary approach and an efficient and effective system for the application of gene technologies that is intended to operate in conjunction with other Australian Government and State and Territory regulatory schemes relevant to GMOs and GM products.

A review of the Act was completed and tabled in Parliament on 27 April 2006 in accordance with the provisions of section 194 of the Act which stipulated that the Ministerial Council must cause an independent review of the operation of the Act as soon as possible after the fourth anniversary of commencement of the Act. The 2006 review recommended that the next review focus on the continued ability of the Act to accommodate emerging trends.

An outcome of the last review recommended focus on the continued ability of the Act to accommodate emerging trends.

Clause 44 of the Intergovernmental Agreement on Gene Technology (the Agreement) requires that the Agreement and the Scheme be reviewed no later than four years after the commencement of the Agreement, with further reviews to be conducted at intervals of no more than five years. As such a review should commence in 2011.

Terms of Reference

The Ministerial Council has established the following Terms of Reference (ToR) for the review of the operation of the Act. The review will be limited to issues within the scope of the current object of the Act which focuses on the health and safety of people and the environment. The review should take into consideration the findings and recommendations of the 2005-06 review. The review will include, but not be limited to:

1. Examine and review:

- **The effectiveness and efficiency** of the way that the regulatory scheme operates, taking account of developments since 2005-06 including:

- a) the national scheme for gene technology regulation in Australia to identify any need for, and opportunities to achieve, improvement in its national consistency, efficiency and effectiveness and coordination; and investigate if the aims of the Agreement to determine these are being achieved;
 - b) emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act, including definitions within the Act, is flexible enough to accommodate changing circumstances; and
 - c) definitions and provisions within the Act to identify possible areas for enhancement in light of experience with the operation of the regulatory system.
- **Whether the object of the Act** is being achieved and whether the regulatory framework stipulated in section 4 of the Act is operating effectively.
 - **The powers of the Act** to ensure that they are sufficient to enforce compliance.
 - **The consultation provisions of the Act** to determine:
 - a) their effectiveness with respect to changes in communication modes, such as various social media tools; the costs and benefits, including the value of advice received; and the transparency and accountability that they provide;
 - b) the functions and roles of the statutory advisory committees; and
 - c) the stakeholders for various applications under the Act and the methodology used to engage them.
 - **The interface between the Act and other Acts and schemes** in Australia (include all States and Territories) that regulate gene technology and its products; and identify any discrepancies, including regulatory gaps and areas needing consistency and harmonisation of provisions.
 - **The regulatory burden** and whether compliance costs for organisations working in gene technology are reasonable and justified compared to benefits achieved and if the regulatory requirements for classes of approval under the Act are commensurate with the level of risk.
2. **Provision of recommendations for amendments to the Act and the Agreement** (including consideration of those recommendations made by State or Territory Parliamentary Committees), or alternatives to legislation, which improve the effectiveness, efficiency, fairness, timeliness and accessibility of the regulatory system.