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

Mr Elton Humphrey
Committee Secretary
Community Affairs Committee
Parliament House
CANBERRA ACT 2600
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Dear Mr Humphrey

Gene Technology Amendment Bill 2007

Thank you for your invitation to make a submission to the Community Affairs Committee Inquiry into the Gene Technology Amendment Bill 2007 (the Bill).

Australia's nationally consistent regulatory scheme for gene technology was developed cooperatively by all jurisdictions and is underpinned by an intergovernmental agreement. Therefore, all nine Governments needed to agree on a response to the 'Statutory Review of the *Gene Technology Act 2000* and the Gene Technology Agreement 2001' (the Review) that was commissioned by the Gene Technology Ministerial Council. I note that, in endorsing the tabling of the Bill, they have in large part accepted the recommendations of the Review

At the end of June 2007, the gene technology regulatory system will enter its seventh year of operation. As the inaugural Gene Technology Regulator, I have appreciated the openness and transparency that is embedded in the Act and, in particular, the amount of information that is made available to the public. It is a point of difference not lost on officials from comparable agencies in the US, Canada, New Zealand, Japan and the European Union, and is of great interest to government representatives from our region who have been charged with designing their countries' regulatory regimes. While decision-making based on sound science is the fundamental basis of Australia's regulatory system, a factor shared with those of other countries, it is the extensive consultative processes and access to information about applications and licences that sets the Australian regulatory system apart.

In keeping with the open and consultative spirit of the Act, the Review process also placed a strong emphasis on consultation. Staff from my office participated in all the public meetings held around Australia by the Review panel to provide a description of the regulatory processes. In addition, I met several times with the Review panel members at their request to elaborate on my submission and discuss their consultation findings.

The Review concluded that the Act and the national regulatory scheme have worked well over the last five years and that no major changes were required. However, the Review did identify some changes intended to improve the operation of the Act at the margin and I am pleased that the Review panel accepted my suggestions (based on operational experience) for some technical amendments.

The Review panel's recommendations which aim to reduce the administrative burden on work that poses very low levels of risk were also informed by my Office's experience of the high degree of cooperative compliance that has been consistently demonstrated by regulated organisations both during and since the transition from voluntary oversight to a legislatively-based system.

In my view, the Gene Technology Amendment Bill 2007 will result in changes that allow me to focus resources on the more complex and higher risk applications of gene technology. Significantly, the changes do not impact on the openness and transparency that is such a highly regarded feature of the system.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator

4 April 2007