EXPLANATORY STATEMENT

Select Legislative Instrument 2009 No. 68

Gene Technology Act 2000

Gene Technology Amendment Regulations 2009 (No. 1)

The *Gene Technology Act 2000* (the Act) establishes the Australian Government's component of a nationally consistent scheme to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms. The Gene Technology Regulator is a statutory office holder responsible for administering the Act.

Subsection 193(1) of the Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the Regulations is to amend the *Gene Technology Regulations 2001* (the Principal Regulations) to allow inspectors from the existing Gene Technology Regulatory Scheme to perform functions under the new Security Sensitive Biological Agents (SSBA) Regulatory Scheme.

In 2002, the Council of Australian Governments (COAG) agreed to review the security of hazardous materials, including harmful biological materials, in Australia. In 2006, a COAG working group issued the *Report on the Regulation and Control of Biological Agents* (the COAG Report) which recommended the establishment of a regulatory scheme for security sensitive biological agents (SSBAs).

The SSBA Regulatory Scheme has been established under Part 3 of the *National Health Security Act 2007* (NHS Act) which provides the legislative response to the recommendations in the COAG Report. The NHS Act is supported by the *National Health Security Regulations 2008* and the SSBA Standards. The SSBA Regulatory Scheme commenced on 31 January 2009.

Part 3 of the NHS Act provides, among other regulatory obligations, for the establishment of an inspection scheme to ensure that the regulated community is complying with the SSBA Regulatory Scheme. The COAG Report recommended that rather than establishing a new inspection regime, inspectors from an existing regulatory scheme be used instead. Due to the similarities between elements of the Gene Technology Regulatory Scheme and the SSBA Regulatory Scheme, the inspectors from the Office of Gene Technology Regulator (OGTR) are the most appropriate for this purpose.

The Gene Technology Regulator has agreed in principle to provide inspectors for the SSBA Regulatory Scheme. However, legal advice indicates that the functions currently conferred on the Gene Technology Regulator under the Act would not provide authority for OGTR inspectors to carry out SSBA inspections. Therefore an amendment to the Principal Regulations is needed to confer a function on the Gene Technology Regulator to provide inspectors for the SSBA Regulatory Scheme.

The Regulations confer a function on the Gene Technology Regulator to make available inspectors to be appointed as SSBA inspectors.

The Gene Technology Ministerial Council, an intergovernmental body comprised of State, Territory and Australian Government Ministers, has given policy approval for the Regulations. Under section 40 of the Intergovernmental Gene Technology Agreement 2001, amendments under the Act must be approved by a special majority of the Gene Technology Ministerial Council.

The Office of Health Protection has consulted with the Office of the Gene Technology Regulator and the States and Territories, through the Gene Technology Standing Committee and the Gene Technology Ministerial Council, to ensure that there is support for the amendment to the *Gene Technology Regulations 2001*. Consultation with entities likely to be inspected under the *National Health Security Act 2007* and the *National Health Security Regulations 2008* occurred in a series of national workshops held in 2008.

The Act specifies no conditions which need to be met before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence on the day after they are registered on the Federal Register of Legislative Instruments.

Authority: Subsection 193(1) of the *Gene Technology Act 2000*