EXPLANATORY STATEMENT

Select Legislative Instrument 2007 No. 128

Subject - *Gene Technology Act 2000*

Gene Technology Amendment Regulations 2007 (No. 1)

The *Gene Technology Act 2000* (the Act) establishes the Australian Government's component of the nationally consistent scheme (the 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 (GMOs).

Section 193 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, 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.

Subsections 4(1) and 4A(2) of the *Acts Interpretation Act 1901*, read together, provide that regulations may be made between the passing and commencement of an Act, as long as such regulations do not commence before the proposed Act upon which they rely for their authority.

In 2005-2006, a statutory review of the Act and the intergovernmental *Gene Technology Agreement 2001* (the Review) was conducted. The Review found that the Act and the national regulatory scheme had worked well in the five years following introduction, and that no major changes were required. However, it suggested a number of minor changes, aimed at improving the operation of the Act at the margin.

On 27 October 2006, the Gene Technology Ministerial Council (GTMC), an intergovernmental body comprised of State, Territory and Australian Government Ministers, gave policy approval for the Gene Technology Amendment Bill 2007 (the Bill) to implement those recommendations to which all governments agreed, as stated in the All of Governments Response to the Review (the Response). The Bill proposes to implement the recommendations requiring legislative change.

Most provisions of the Bill are scheduled to commence on 1 July 2007, with the remaining provisions scheduled to commence on 1 January 2008, or on the day on which the proposed Act receives Royal Assent.

The purpose of the Gene Technology Amendment Regulations 2007 *(No. 1)* (the Amendment Regulations) is to amend the Gene Technology Regulations 2001 (the Principal Regulations) to give effect to those recommendations of the Review directly affecting the Regulations, and to make consequential amendments necessitated by amendments to the Act. The amendments reflect the agreement reached between the Commonwealth, State and Territory Governments, as indicated in the Response.

The Act specifies no conditions that need to be satisfied before the power to make the proposed Regulations may be exercised. However, Clause 33 of the Gene Technology Agreement 2001 (the Agreement) requires any Party to that Agreement (including the Commonwealth) that proposes to amend its legislation forming part of the Scheme to submit the proposed amendments to the Gene Technology Ministerial Council (the Ministerial Council; composed of relevant ministerial representatives from the Commonwealth and States and Territories) for consideration before introduction of the amendments. The Amendment Regulations were approved in accordance with the Agreement by the Ministerial Council on 4 May 2007.

The Amendment Regulations specify:

- that the National Health and Medical Research Council's (NHMRC's) role be changed from a prescribed agency to one where the Gene Technology Regulator (the Regulator) can seek its advice as appropriate (recommendation 5.4 of the Review);
- the matters the Regulator must have regard to in preparing a risk assessment and risk management plan (after the removal of the matters from the Act resulting from recommendation 5.5 of the Review);
- changed timeframes within which the Regulator is required to consider licence applications to deal with GMOs, and a new timeframe for variations to licences (recommendations 5.7, 5.8 and 5.9 of the Review);
- that there be no legislative requirements on exempt dealings beyond a listing in the Regulations (recommendation 6.1 of the Review);
- a requirement to include a report of all notifiable low risk dealings (NLRDs) assessed in the last financial year in the accredited organisation's annual report, and to maintain an up-to-date list of all NLRDs which have been conducted, replacing the requirement to notify NLRDs to the Regulator before commencement of the dealing (recommendation 6.2 of the Review);
- consequential amendments needed to implement some recommendations and necessitated by changes proposed to the Act by the Bill (recommendations 5.2, 5.5 and 5.6), including:
    - splitting the NLRD category into two classes;
    - movement of some exempt dealings to the NLRD category; and
    - combining of the Gene Technology Ethics and the Gene Technology Community Consultative Committees into the new Gene Technology Ethics and Community Consultative Committee.

The Review was conducted by an independent panel of three people and considered almost 300 submissions from members of the public, industry and other stakeholders. These were analysed by the panel and developed into issue papers. A period of national consultation followed, whereby public forums were held at numerous locations around Australia. This allowed the Review to hear, first hand, a range of views of interested parties, including State governments, industry, researchers, farm groups, non government organisations and consumers. Once the Review was completed, there followed a period of explicit consultation with the States and Territories on how best to implement the recommendations of the Review. This led to the development of the draft Gene Technology Amendment Bill 2007 and the Gene Technology Amendment Regulations 2007 which were finally agreed to by all States and Territories after a further consultation period. The Office of Business Practice Regulation was also consulted and determined that no Regulation Impact Statement was required (RIS ID: 8028).

Details of the Amendment Regulations are set out in Attachment A.

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

ATTACHMENT A

Details of the proposed *Gene Technology Amendment Regulations 2007 (No. 1)*

Regulation 1 – Name of Regulations

This regulation provides that the title of the Regulations is the *Gene Technology Amendment Regulations 2007 (No. 1)*.

Regulation 2 – Commencement

This regulation provides for the Amendment Regulations to be scheduled to commence on the same day as the corresponding sections of the Bill as follows:

(a) Schedules 1 and 2 – on 1 July 2007, or on the day after the day on which the proposed Act receives Royal Assent, whichever is the later;
(b) Schedule 3 – on a single day to be fixed by Proclamation, which must be before 1 January 2008, otherwise on 1 January 2008.

Regulation 3 – Amendment of *Gene Technology Regulations 2001*

This regulation provides that the Principal Regulations are amended as set out in the Schedules.

Schedule 1 – Amendments

Item [1] – Paragraph 6(1)(c)

Removal of paragraph 6(1)(c) of the Principal Regulations removes the legislative requirements for using exempt dealings in accordance with any technical or procedural guidelines and implements recommendation 6.1 of the Review.

Items [2] – Regulation 8

Amendments to Principal Regulation 8 change the timeframes in which the Regulator must issue, or refuse to issue, a licence for intentional release applications under s 43 of the Act. The amendments implement recommendations 5.7, 5.8 and 5.9 of the Review. The new timeframes are:

- 150 days for limited and controlled release applications not posing significant risks;
- 170 days for limited and controlled release applications posing significant risks; and
- 255 days for applications for intentional releases that are not limited and controlled.

Item [3] – Regulation 8

This change to Principal Regulation 8 makes clear that a limited and controlled release application is one to which section 50A of the Act applies and is a consequential amendment necessary to implement recommendation 5.6.

Item [4] – Regulation 9

This change removes the NHMRC as a prescribed agency, in light of NHMRC's practical experience as a prescribed agency. The Regulator would be able to seek advice from the NHMRC as appropriate. These changes implement recommendation 5.4 of the Review.

Item [5] – Regulation 9A

Item 40 of the Bill amends paragraph 51(1)(a) of the Act to provide that the Regulations may prescribe matters that the Regulator must have regard to in preparing a risk assessment and risk management plan (RARMP). This item inserts a new Regulation for this purpose. Item 36 of the Bill would repeal section 49 of the Act, which lists matters that the Regulator must have regard to in satisfying itself as to whether a dealing may pose significant risk, and which must also be considered in preparing the RARMP. This item makes the consequential change that ensures these matters are referred to by the Regulations. This change is necessitated by changes to the Act required to implement recommendation 5.5 of the Review.

Item [6] – Regulation 11A

This item inserts a new regulation that introduces a timeframe of 90 days within which the Regulator must notify of its decision to either vary or refuse to vary a licence made under s 71(7) of the Act. This change implements recommendation 5.9 of the Review.

Item [7] – Regulation 13 and Regulation 13A

The new Regulation 13 of this item removes the requirement to notify NLRDs to the Regulator before commencing the dealing. This item also inserts a new Regulation (Regulation 13A) that introduces a requirement to include a report of all NLRDs assessed in the last financial year in the accredited organisation's annual report, and to maintain an up-to-date list of dealings which have been conducted, for inspection and auditing purposes. These changes are necessary to implement recommendations 6.2 of the Review.

Recommendation 6.1 of the Review required removal of the requirement in paragraph 6(1)(c) by item 1 of the Amendment Regulations and that the Regulator undertake regular reviews of the list of exempt dealings in the Regulations. In reviewing the list, the Regulator found that it was not appropriate for some of the dealings to continue to be listed as exempt dealings once paragraph 6(1)(c) was removed, necessitating some consequential amendments to the exempt dealings and NLRD categories (see items 8-17 of Schedule 1). Dealings removed from the exempt list have been moved to the NLRD category. The new Regulation 13 provides similar controls to the dealings moved from the exempt category to the NLRD category to those provided for under the previous Regulation 6(1)(c). This is achieved by creating a new subtype of NLRDs, in paragraph 13(2)(a), which may be conducted in physical containment level 1 facilities.

Items [8-13]

These items make the necessary amendments to the Principal Regulations resulting from the removal of Regulation 6(1)(c) and the addition of the new Regulation 13.

These items remove from the exempt category:

- dealings with a genetically modified laboratory mouse or a genetically modified laboratory rat, unless:
    - an advantage is conferred on the animal by the genetic modification; or
    - as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent; and
- dealings involving a host/vector or host/vector system able to transduce human cells.

Item [1] of Schedule 2 of the Amendment Regulations includes these dealings in the new subcategory of NLRDs which may be conducted in physical containment level 1 facilities.

Items [14-17]

These items [14-17] renumber Part 1 and Part 2 of the Principal Regulations, as a new Part 1 has been added to the Principal Regulations by item [1] of Schedule 2 of the Amendment Regulations.

Schedule 2 – Amendments

A review by the Regulator of the exempt dealings category, consistent with recommendation 6.1 of the Review, found that the removal of the controls following the deletion of Regulation 6(1)(c) required some dealings to be removed from the exempt category to ensure the health and safety of people and the environment. These dealings have been moved to the new NLRD subcategory, which may be conducted in physical containment level 1 facilities (referred to at paragraph 13(2)(a)(i) as introduced by item [7] of Schedule 1, see above), providing a similar level of containment as the Principle Regulations provide for exempt dealings. This Schedule makes the necessary changes to the description of NLRD in the Principal Regulations.

Item [1]

This item inserts a new Part 1 into Schedule 3 of the Principal Regulations, describing the NLRDs that are suitable to be conducted in physical containment level 1 facilities. These are dealings that have been moved from the exempt category, involving:

- genetically modified laboratory mice or rats unless the genetic modification confers an advantage on the animal or enables the animal to secrete or produce an infectious agent;
- hosts/vector systems that are listed as suitable for exempt dealings, if the donor nucleic acid confers an oncogenic modification;

- replication defective viral vectors in tissue culture (human or animal), unless the vector is a retroviral vector or the donor nucleic acid confers an oncogenic modification.

Item [2]

This item changes the heading of Part 1 of the Principal Regulations (which would be renumbered as Part 2 by item [14] of the Schedule 1 of the Proposed Regulations) to describe NLRDs that are suitable for physical containment level 2 facilities.

Item [3]

This item amends the note at the start of the renumbered Part 2, consequential to the renumbering of Parts of Schedule 3 of the Principle Regulations (associated with addition of a new Part 1 by item [1] of Schedule 2 of the proposed regulations).

Item [4]

This item amends the renumbered Part 2 to describe those NLRDs which may be conducted in physical containment level 2 facilities, consequential to the introduction of a new subcategory of NLRDs by item [7] of Schedule 1 and item [1] of Schedule 2 of the Amendment Regulations.

Items [5 and 6]

These items omit paragraph 2(e)(iii) of Part 1.1 of the Principal Regulations to remove reference to vectors that, due to item [13] of Schedule 1 of the Amendment Regulations, are no longer be listed in the exempt category (viral vectors able to transduce human cells).

Item [7]

This item substitutes a new paragraph 2.1(i) in the renumbered Part 2 of the Principal Regulations to capture those dealings involving defective viral vectors able to transduce human cells in cell culture (animal or human) in the NLRD category suitable for conducting in physical containment level 2 facilities where:

- the vector is a retroviral vector; or
- the donor nucleic acid confers an oncogenic modification.

This change was required due to the exclusion from the list of exempt host/vector systems, by item [13] of Schedule 1 of the Proposed Regulations, of viral vectors able to transduce human cells.

Items [8-11 and 13]

These items amend numbering in the renumbered Part 3 of Schedule 3 of the Principal Regulations to take into account the addition of the new Part 1 by item [1] of Schedule 2 of the Amendment Regulations.

Item [12]

This item excludes all dealings involving a lentiviral vector not able to transduce human cells, in addition to those able to transduce human cells, from the NLRD category, unless specific safeguards are in place to prevent generation of replication competent virions through recombination.

Schedule 3 – Amendments

Item [1]

This item makes a consequential amendment to the Principal Regulations so that the definition of expert advisers in the Amendment Regulations refers to the new section of the proposed Act relating to the creation of the new Gene Technology Ethics and Community Consultative Committee (GTECCC) that mentions expert advisers.

Items [2-6]

These items make consequential amendments to the Principal Regulations necessary for the Regulations to remain consistent with the Act after the creation of the new GTECCC, as indicated in recommendation 5.2 of the Review.