Gene Technology Technical Advisory Committee

COMMUNIQUE
No. 21

This is the 21st communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 31st meeting of GTTAC, held on 4 December 2007 and matters considered out of session in July and September 2007.

GTTAC is a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All Committee members and expert advisers hold office on a part-time basis.

The Regulator receives input from GTTAC on applications for licences to conduct dealings with genetically modified organisms (GMOs), as well as comments on the Risk Assessment and Risk Management Plan (RARMP) that is prepared for each of these applications.

The purpose of this Communiqué is to provide a brief overview of the applications and RARMPs considered by GTTAC and the advice the Committee has provided to the Regulator with regard to those applications and RARMPs.

The Communiqué also summarises other major issues discussed by GTTAC.

Advice on RARMPs

Advice on DNIR 179/2003 Variation RARMP

GTTAC considered the RARMP prepared in response to the following application:

DNIR 179/2003 – *Ex vivo* retroviral transduction of CD34 selected haematopoietic stem cells for clinical gene therapy – variation to original application

DNIR 179/2003, issued to The Children's Hospital at Westmead in June 2003, licenced the laboratory component of the trial. The licence holder has applied for a variation to the licence conditions to enable the clinical trial to proceed.

The aim of the clinical trial is to introduce genes into CD34 haematopoietic stem cells to treat patients with X-linked Severe Combined Immunodeficiency and to provide resistance to alkylating drugs used in cancer therapy. The proposed dealings involve the *ex vivo* transduction of CD34+ cells from patients who are undergoing chemotherapy with a replication defective vector, followed by *in vivo* administration of the transduced cells to the patient from whom they were originally

isolated. Authorisation from the TGA would also be required before administration to patients in a clinical trial could proceed.

GTTAC discussed the application and advised the Regulator that:

- Further information regarding the methodologies and the results of similar clinical trials carried out overseas should be requested.
- Comment should also be sought from the Cellular Therapies Advisory Committee of the NH&MRC

Advice on Applications

- **Molecular identification & characterisation of the virulence and host range determinants of SARS and SARS-like *Coronaviruses* (DNIR 427/2007)**

- **Identification of virulence factors for *Henipaviruses* (DNIR 428/2007)**

The Committee discussed two licence applications from CSIRO Livestock Industries, Geelong, involving the generation of genetically modified viruses. Both applications seek to generate mutant and chimeric viruses, to characterise viral infectivity in mammalian tissue culture cells and to examine changes in viral pathogenesis and tissue tropism by infecting animals (ferrets or bats). The dealings are proposed to occur at the Australian Animal Health Laboratories in Geelong, in PC3 and PC4 containment facilities.

GTTAC advised the Regulator that additional information on the sequence of planned experiments would be useful in preparing the RARMP.

Review of Biology Documents

GTTAC reviewed a number of Biology Documents prepared by the OGTR. The documents are based on the available scientific literature and serve as a key reference on the properties and characteristics of the unmodified parent organism, providing a 'baseline' for comparison in the conduct of risk assessments for GMOs. The existing Biology Documents for cotton, canola, wheat, sugarcane, papaya and pineapple have been updated. New documents have been developed for banana and zebrafish. Feedback from GTTAC will be incorporated into the documents before they are published on the OGTR website.

Committee members commented favourably on the documents and encouraged the Regulator to make these documents as widely available as possible.

Presentation

An information paper on the number of volunteer plants found during the post-harvest monitoring period for limited and controlled releases of GM canola and cotton was presented to GTTAC

Enquiries and Risk Assessment and Risk Management Plans

For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please phone the OGTR on 1800 181 030. The RARMPs are also available electronically from our website at http://www.ogtr.gov.au