COMMUNIQUE
No. 24

This is the 24th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 34th meeting of GTTAC, held on 15 October 2008.

GTTAC is a statutory advisory committee established under the *Gene Technology Act 2000* (the Act) to provide scientific and technical advice 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 advice from GTTAC on Risk Assessment and Risk Management Plans (RARMPs) prepared for licences to conduct dealings with genetically modified organisms (GMOs).

The purpose of this Communiqué is to provide a brief overview of the applications and RARMPs considered by GTTAC and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any resolutions the Committee has provided to the Regulator with regard to those applications and RARMPs.

The Communiqué also provides an overview of any other major issues discussed by GTTAC.

Dealings Involving the Intentional Release of Genetically Modified Organisms

Dealings Involving the Intentional Release of GMOs (DIRs) involve the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

The RARMP for every DIR licence application is released for public comment as part of the consultation process. Information on how to obtain copies of applications and RARMPs for DIRs is provided at the end of this document.

GTTAC Advice

The Regulator must seek GTTAC advice on the preparation of the RARMP for all applications, except for those that the Regulator has determined may be assessed as a 'limited and controlled' release (section 50A of the Act). The Regulator must seek GTTAC advice on RARMPs prepared in respect of all DIR applications

Advice on Applications

GTTAC considered the following commercial release applications:

DIR 090 – Commercial release of rose genetically modified for altered flower colour

The application, from Florigene Pty Ltd, involves the commercial release of a Hybrid Tea Rose genetically modified to alter flower colour from pink to purple/blue. GTTAC noted that Florigene propose to licence only one grower to supply cut flowers through the normal commercial distribution chain, but that it would be possible for home gardeners to propagate the GM rose from cut flower stems and that it may be grown in gardens throughout Australia.

GTTAC advised the Regulator that the risk assessment should be done on the assumption that, if released commercially, the GM rose would be widely grown in home gardens. The committee also advised that, although there is potential for exposure of humans and animals to products derived from the GM flowers, but that no issues were identified which might give rise to adverse outcomes.

DIR 091 – Commercial release of Widestrike™ Insect Protection cotton.

Dow AgroSciences have applied to release GM cotton into the Australian environment without specific containment measures south of latitude 22° South. The GM cotton contains two genes that have been shown to provide resistance to lepidopteran pests of cotton plants.

GTTAC noted that the GM cotton also contained a gene which may confer tolerance to specific herbicides and suggested that more information should be sought about the level of tolerance expressed under field conditions. GTTAC advised the Regulator that the following items should be considered in the development of the RARMP:

- The specificity of the combination of the two Cry proteins in the GM cotton and potential toxicity to non-target organisms under Australian conditions;
- The tolerance to glufosinate ammonium, conferred by the presence of two full length copies of the *pat* gene and risks that may be associated with this trait;
- The potential for unintended presence of the GM cotton in areas north of latitude 22° South and the possible impacts of any unintended presence north of this latitude; and
- The impact of this GM cotton if crossed with other previously commercially approved GM cotton lines which have insect resistance and herbicide tolerance traits (DIRs 062/2005 and 066/2006).

Advice on Consultation RARMP's

GTTAC considered the Consultation RARMPs prepared in response to the following applications:

DIR 079/2007 – Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance.

GTTAC considered the consultation RARMP prepared in response to an application from Bayer CropScience Pty Ltd for a limited and controlled release of cotton to take place at one site in the Narrabri area of New South Wales.

GTTAC advised the Regulator that the consultation RARMP adequately identifies and addresses risks to human health and safety and risks to the environment from the proposed release.

DIR 085 – Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil

GTTAC considered the consultation RARMP prepared in response to an application from CSIRO for a limited and controlled release of one line of cotton genetically modified for altered fatty acid composition of the cottonseed oil. The proposed site is in the Narrabri area of New South Wales.

GTTAC discussed the possibility that the altered fatty acid profile of the cottonseed may lead to changes in the dormancy or germination potential of the GM cotton, and concluded that the proposed licence conditions are adequate. GTTAC advised the Regulator that the consultation RARMP adequately identifies and addresses risks to human health and safety and risks to the environment.

DIR 086 – Limited and controlled release of maize genetically modified to investigate gene function

GTTAC considered the consultation RARMP prepared in response to an application for a limited and controlled release of 11 GM maize lines at a CSIRO research facility in the Australian Capital Territory.

GTTAC advised the Regulator that the consultation RARMP adequately identifies and addresses risks to human health and safety and risks to the environment.

DIR 089 – Limited and controlled release of white clover genetically modified to resist infection by Alfalfa mosaic virus

GTTAC considered the consultation RARMP prepared in response to an application from the Victorian Department of Primary Industries for a limited and controlled release of one line of white clover genetically modified to resist infection by Alfalfa mosaic virus (AMV). The trial is proposed to take place in the Corowa area of New South Wales.

GTTAC advised that more information is needed about the extent to which AMV limits growth of white clover in non-agricultural environments.

Out of Session Advice

GTTAC noted that Out of Session advice had been provided on the following consultation RARMPs:

- **DIR 078 - Limited and controlled release of sugarcane genetically modified for altered sugar production; and**
- **DIR 081 – Limited and controlled release of cotton genetically modified for enhanced water use efficiency**

Other Advice:

Dealings not involving the intentional release of genetically modified organisms

Dealings not involving the intentional release of GMOs (DNIRs) are dealings that are usually undertaken within a facility where the organism is physically contained and where the personnel involved in the dealing have been assessed as having adequate training and experience for the task.

DNIR 449 – Phase 1 study of autologous T lymphocytes with an anti LeY chimeric receptor gene for patients with Multiple Myeloma, Acute Myeloblastic Leukaemia or high-risk Myelodysplastic Syndrome

GTTAC considered the RARMP prepared in response to an application to conduct a Phase 1 clinical trial involving six patients. The trial would test the safety and efficacy of GM T-lymphocytes for the treatment of tumours in patients with Multiple Myeloma, Acute Myeloblastic Leukaemia or high-risk Myelodysplastic Syndrome.

GTTAC advised the Regulator:

- to seek clarification of the exclusion criteria for the trial, particularly with reference to female patients of childbearing age;
- that the GM cells should be screened to exclude replication competent virus before administration to patients.

GTTAC noted that the applicant will conduct the trial as per the clinical trial CTN/CTX framework administered by the Therapeutic Goods Administration (TGA).

NB: Safety issues related to clinical trial participants form part of the ethical and scientific review conducted by Human Research Ethics Committees. In addition, the TGA may seek additional information and clarification about safety or other aspects of clinical trials that are notified as part of the CTN/CTX process.

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