Gene Technology Technical Advisory Committee

COMMUNIQUE
No. 19

This is the nineteenth communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty-ninth meeting of GTTAC, held on 7 December 2006.

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 Plans (RARMPs) that are prepared for these applications and form the basis of the Regulator's decision whether to issue a licence.

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 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) are dealings that are undertaken outside of a certified physical containment facility. DIRs may involve the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

A Risk Assessment and Risk Management Plan (RARMP) is prepared in respect of every licence application for a DIR licence and released for public comment as part of the consultation process for these applications. Information on how to obtain copies of applications and RARMPs for DIRs is provided at the end of this document.

Advice on Applications

DIR071/2006 – Limited and controlled release of drought tolerant wheat

The OGTR has received an application from Department of Primary Industries (DPI) Victoria to release up to 30 lines of GM bread wheat (*Triticum aestivum* L.) lines into the environment on a limited scale and under controlled conditions.

The proposed release would take place at 2 sites over an area of 1500m^2 in the Shire of Horsham and an area of 750m^2 in the Shire of Mildura, over one season (May 2007 – March 2008).

The aim of the trial is to evaluate the agronomic performance, including yield analysis of the GM wheat lines under rain-fed, drought prone conditions. Seed will also be collected and retained for seed increase or further experimentation (subject to additional approval).

The Committee was informed that all containment measures proposed by the applicant would be assessed in the course of the evaluation and consistent measures would be applied commensurate with the assessed level of risk.

The Committee noted that it would comment further on the proposed conditions when the RARMP was provided to the Committee in 2007.

Advice on RARMPs

GTTAC considered the consultation RARMPs prepared by the OGTR in response to the following applications:

DIR 068/2006 – Limited and controlled release of genetically modified torenia with altered flower colour

GTTAC considered the RARMP for licence application DIR068/2006 received from Florigene Pty Ltd to carry out a trial of nine genetically modified (GM) torenia lines (*Torenia X hybrida*) with altered flower colour at a single site in Darebin, Victoria, from October 2007 to May 2008 under limited and controlled conditions.

The proposed field trial would involve growing up to 200 GM plants individually in hanging baskets suspended over gravel or concrete in an area not exceeding $100m^2$. The aim of the proposed field trial was to assess outdoor performance. Horticultural characteristics such as plant size, number and longevity of flowers, flower colour stability and susceptibility to pests and diseases would be evaluated compared to the non-GM parent plant.

The Committee noted that there was potential for rooting if the plant was grown in moist soil with stems attached. However if the stem was broken off, propagation would require manual intervention and the correct environment to persist. Members noted that the applicant had provided information to indicate that detached stem pieces or cuttings cannot survive under natural conditions.

The Committee considered the possibility of dissemination of plant segments by birds that might give rise to vegetative reproduction of the GMO. The Committee concluded that this posed a negligible risk as torenia is a summer annual plant and will not survive the cold winter temperatures of Victoria.

GTTAC suggested that further information on the current distribution of non-GM varieties of torenia might be obtained.

GTTAC advised the Regulator that the Committee agreed with the risk assessment and that the proposed licence conditions are adequate to contain the release to the location, size and duration of the trial requested by the applicant.

DIR 070/2006 – Limited and controlled release of GM sugarcane with altered plant architecture, enhanced water or nitrogen use efficiency.

GTTAC considered the RARMP for licence application DIR070/2006 received from the BSES Ltd seeking approval for the limited and controlled release of up to 2500 GM sugarcane lines in to the environment under limited and controlled conditions. The sugar cane lines have been modified to alter shoot architecture (shoot number, stalk size and height), and enhance water or nitrogen use efficiency. The trial is proposed to

take place at up to 3 sites per cropping cycle from March 2007 to November 2010 in the local government areas of Bundaberg, Caboolture and/or Cairns, Queensland.

Members advised that the cross pollination of non GM sugar cane was unlikely as sugar cane had very low fertilisation and the gene flow, if any, would pose negligible risk.

Members noted that this trial was an early stage project and further allergenicity data would be required if any commercial release was applied for in the future.

GTTAC advised the Regulator that the committee agreed with the risk assessment and that the proposed licence conditions are appropriate to contain the release to the location, size and duration of the trial requested by the applicant.

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 certified facility (so that 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. These are typically laboratory-based projects.

DNIR 402/2006 – Single armed, multi-centre, open label clinical study evaluating the safety and tolerability of NovaCaps® in patients with inoperable pancreatic carcinoma

An application has been submitted to the OGTR to conduct a Phase I clinical study into the safety and tolerability of an encapsulated cell therapy product (NovaCaps®) in patients with inoperable pancreatic carcinoma who are receiving the chemotherapeutic drug ifosfamide.

The National Health and Medical Research Council's Gene and Related Therapies Research Advisory Panel (GTRAP) provided advice on the protocol proposed in the dealing.

GTTAC considered that the risk to patients would be low. Also due to the nature of the GMO, no significant risks were identified to medical staff undertaking the dealing or to any other people or the environment in the event of an unintentional release is negligible.

GTTAC advised the Regulator that the RARMP adequately identified and managed the risks associated with the proposed clinical trial.

DNIR 401/2006 – Transmissible Genetic Elements in Bacteria

The OGTR has received an application seeking to further characterise transmissible genetic elements responsible for antibiotic resistance in medically significant bacterial isolates.

The aim of the proposed dealing is to characterise antibiotic resistance-associated genetic loci such as resistance genes and mobile genetic elements in bacteria.

The Committee advised the Regulator that PC2 containment and work practices were adequate for the stacking of multiple resistance genes into risk group 2 human eubacterial pathogens.

Presentations

The following presentations were made to GTTAC:

- Feedback from the 2nd National Institutional Biosafety Committee Forum held in Canberra on 15 and 16 November, 2006.

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 Free-call hotline on 1800 181 030. The RARMPs are also available electronically from our website at http://www.ogtr.gov.au