Gene Technology Technical Advisory Committee

COMMUNIQUE
No. 16

This is the sixteenth communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty-sixth meeting of GTTAC, held on 6 December 2005, and matters considered out of session in August 2005.

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

Dealings Not Involving the Intentional Release of Genetically Modified Organisms (DNIRs)

DNIRs are dealings that are undertaken within a physical containment facility. DNIRs do not involve the release of a GMO into the environment.

A Risk Assessment and Risk Management Plan (RARMP) is prepared in respect of every licence application for a DNIR licence. GTTAC is consulted on DNIRs which involve novel GMOs or clinical trials, or which are likely to be contentious.

Advice on RARMPs

Advice on Genetically Modified (GM) Vaccine

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

DNIR 369/2005 – A phase 2 study to evaluate the efficacy and safety of Merck Adenovirus serotype 5 HIV-1 vaccine in adults at high risk of HIV-1 infection

DNIR 370/2005 – A randomised study of therapeutic immunisation and treatment interruption among subjects diagnosed with acute or recent HIV infection

The OGTR has received two applications from St Vincent's Hospital, Sydney, to conduct clinical trials of a human adenovirus vaccine in a clinical facility as part of an international study.

The aim of the proposed dealings, which utilise the same GMO, is to conduct a three dose multi-centre randomised placebo-controlled clinical trial to test the safety, efficacy and tolerability of a recombinant HIV-1 vaccine based on the human Ad5 serotype adenovirus.

DNIR 369/2005 would test the ability of the vaccine to decrease the HIV-1 viral load of trial subjects who are inoculated with the vaccine and who subsequently become infected with HIV-1.

Under DNIR 370/2005, a therapeutic trial would be conducted to determine whether the vaccine can prime the immune system to suppress HIV replication and decrease viral load following interruption of anti-retroviral therapy.

Aspects of the genetic modification proposed by this application are protected by a declaration of confidential commercial information, but were made available to GTTAC.

GTTAC discussed these applications from St Vincent's Hospital (Sydney) and advised the Regulator that:

- the risk assessment identifies all risks associated with the use of the GMO; and
- the Committee agrees with the proposed licence conditions.

GTTAC also requested to be notified of the number of people to be involved in the trials in Australia.

Dealings Involving the Intentional Release of Genetically Modified Organisms (DIRs)

DIRs are dealings that are undertaken outside of a certified physical containment facility. DIRs 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 RARMPs

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

Advice on GM Fowl Adenovirus

DIR 046/2003 – Limited and controlled release of GM fowl adenovirus (FAV)

Imugene Ltd has applied for a licence to trial a GM fowl adenovirus (FAV). The proposed trial involves the limited and controlled release of a GM fowl adenovirus at an animal containment facility in Werribee, Victoria.

The purpose of the proposed release is to investigate the ability of GM FAV8 to boost the immune system of inoculated chickens and to provide information on the shedding and spread of the GM virus. The adenovirus contains the chicken interferon gamma (Ch IFN-γ) gene which produces the Ch IFN-γ protein. Imugene anticipates that expression of Ch IFN-γ protein in inoculated chickens will stimulate their immune system and assist them to use food more efficiently, thereby increasing their rate of weight gain.

The proposed trial would involve the inoculation of up to 1500 chickens with the GM FAV8 between 1 February 2006 and 30 April 2006. Chickens used in the trial would be obtained from commercial flocks and would have already been vaccinated against several other viruses. Sentinel animals would be used to

confirm that GM FAV8 cannot be transmitted to animals outside the known host range of the virus.

The applicant proposes to run the trial for a period of 49 days, after which all animals involved in the trial would be euthanased and incinerated following the removal of tissue samples for analysis. At the completion of the study, all litter would be incinerated and the facility would be decontaminated and monitored.

GTTAC advised the Regulator that:

- The risk assessment identifies all risks associated with the release.
- Monitoring of the site after decontamination is demonstrated to be complete, and the inclusion of sheep as sentinel animals are not necessary.
- The Committee agrees with the other proposed licence conditions.

The Committee considers that more data would be required on the effects of the virus on the host and the ability of the virus to infect other bird species to assess applications for future larger scale releases.

Advice on GM Cotton

DIR 059/2005 – Commercial release of herbicide tolerant (Roundup Ready Flex® MON 88913) and herbicide tolerant/insect resistant (Roundup Ready Flex® MON 88913/Bollgard II®) cotton south of latitude 22° South in Australia

The OGTR has received an application from Monsanto Australia Ltd for commercial release of GM Roundup Ready Flex® (herbicide tolerant) and Roundup Ready Flex®/Bollgard II® (herbicide tolerant/insect resistant) cotton. The proposed release would involve a phased introduction commencing with up to 20,000 hectares in cotton growing regions of New South Wales and southern Queensland south of latitude 22° South. If approved, planting is anticipated to commence in spring 2006, and planting in subsequent years may extend to other areas south of latitude 22° South.

The applicant has also proposed to transport cotton seed from the release to areas north of latitude 22° South for use as stockfeed.

Roundup Ready Flex® cotton contains two copies of a gene which provides tolerance to glyphosate, the active ingredient in Roundup Ready® herbicide. It differs from the previously released Roundup Ready® cotton in that tolerance to Roundup Ready® herbicide is prolonged beyond the four leaf growth stage, offering farmers a greater window during which the herbicide can be applied.

Monsanto has also submitted an application to the Australian Pesticides and Veterinary Medicines Authority to allow the use of Roundup Ready® herbicide on GM cotton beyond the four leaf stage.

GTTAC advised the Regulator that:

- The risk assessment identifies all risks associated with the commercial release.
- The Committee agrees with the proposed licence conditions.

Advice on GM Roses

DIR 060/2005 Field Trial - Propagation and trial of imported GM rose varieties

Florigene Ltd is seeking approval for the limited and controlled release of three GM rose lines. The imported rose lines are of Hybrid Tea and Floribunda varieties and have been genetically modified to alter the flower colour and produce blue pigments.

The aims of the proposed release are to: evaluate the productivity, morphology and viability of the GM rose lines in an Australian green house facility; conduct limited propagation; and generate data to support a possible future application for large scale release.

The three rose lines would be grown in pots in an enclosed, insect-proof greenhouse in the Yarra Ranges Shire, Victoria. Approximately 100 plants of each GM rose line are proposed for release, along with 100 plants each of the two non-GM parental rose varieties, and 10 plants each of two other non-GM rose varieties.

GTTAC advised the Regulator that:

- the risk assessment identifies all risks associated with the release; and
- the Committee agrees with the proposed licence conditions.

Advice on Applications

Advice on Wheat

Intentional release of Genetically Modified Wheat

(DIR 061/2005)

The OGTR has received an application from Grain Biotech Australia Pty Ltd for a limited and controlled release of up to 20 lines of GM salt tolerant wheat plants. The trial would take place on a farm site in the Corrigin Shire, Western Australia, and cover a maximum area of 0.45 hectares.

The purpose of the proposed trial is to evaluate the wheat lines for salt tolerance and agronomic performance. The GM wheat lines, along with

controls of non-GM wheat lines, would be planted in soil with a salinity gradient. The trial would run for one season, from April 2006 to December 2006.

The GM wheat lines have been genetically modified to contain an additional copy of the *oat* gene, which enhances synthesis of the enzyme ornithine amino transferase and leads to increased production of proline. Proline is an osmoprotectant, a molecule which can protect plant proteins and membranes from the effects of high salt concentrations and enable plants to grow in saline soils. The GM wheat lines also contain either the *cah* selectable marker gene, which provides resistance to the herbicide cyanamide, or the *nptII* selectable marker gene, which provides resistance to antibiotics such as neomycin and kanamycin.

None of the material harvested from the trial, including the seed, would be used for food for either humans or animals. Any material which is not used for research would be destroyed.

GTTAC discussed this application and advised the Regulator that:

- issues relating to containment, seed dormancy and reproductive isolation need to be considered.

GTTAC also noted that the application is very similar to DIR 053/2004.

Other Advice

The OGTR sought GTTAC advice on the RARMP for the following DIR application in an out-of-session package in August 2005.

DIR 058/2005 – Limited and controlled release of insect resistant (VIP) GM cotton

Deltapine Australia Pty Ltd is seeking approval for the intentional release of three GM insect resistant (VIP) cotton lines into the environment, on a limited scale and under controlled conditions.

The cotton lines have been modified to contain the *vip3A* gene from the bacterium *Bacillus thuringiensis*, for insect resistance, and the *aph4* gene from *Escherichia coli* for antibiotic resistance.

Deltapine proposes to conduct the release on up to two sites in the Narrabri Shire, New South Wales, and/or the Emerald Shire, Queensland. The total area of the release would be up to 1 hectare, and the trial would take place over the 2005-06 cotton growing season.

The aim of the proposed release is to produce seed for future releases, which would be subject to future assessments and approvals.

GTTAC advised the Regulator that:

- the risks posed by the proposed dealings under DIR 058 are negligible; and
- the Committee agrees with the proposed licence conditions.

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