GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE
No. 15

This is the fifteenth communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty-fifth meeting of GTTAC, held on 1 August 2005 and matters considered out of session in May 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 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 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

Advice on GM cotton

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

- **DIR 056/2004 - Field trial - herbicide tolerant (LLCotton25) and herbicide tolerant/insect resistant (LLCotton25/Bollgard II®) cottons**

The OGTR has received an application from Bayer CropScience for the limited and controlled release of herbicide tolerant (LLCotton25) and herbicide tolerant/insect resistant (LLCotton25/Bollgard II®) cottons into the environment. The aims of the trial are to transfer the introduced traits (insect resistance and herbicide tolerance) into elite Australian cotton varieties; to test the agronomic performance of the GM cottons; to conduct demonstration trials for farmers, to produce seed for future releases (which would require separate applications and approval processes); and to conduct tests with material from the GM cottons in the laboratory.

A maximum total area of 500 hectares would be planted in each of the 2005/06 and 2006/07 summer growing seasons in the cotton growing regions of New South Wales (NSW) and southern and central Queensland (Qld).

LLCotton25 cotton contains a single copy of a gene (*bar*), derived from a common soil bacterium. The protein encoded by the bar gene is an enzyme[1] (PAT) that confers tolerance to glufosinate ammonium (the active constituent in herbicides such as Basta® and Liberty®). The PAT enzyme converts glufosinate ammonium into an inactive form and thus allows the application of glufosinate ammonium-containing herbicide for the control of weeds that emerge in the crop, without damaging the crop itself.

LLCotton25/Bollgard II® cotton was produced by crossing of LLCotton25 with GM Bollgard II® cotton via conventional breeding. This process introduces two genes derived from another soil bacterium that produce insecticidal proteins which are highly specific and toxic to the major caterpillar pests of cotton.

Limited and controlled releases of LLCotton25 were previously approved under licences DIR 015/20002 and DIR 038/2003 (both issued to CSIRO). These field trials are being conducted from 2002 to 2005 in NSW and Qld. The other parent GMO, Bollgard® II cotton, was approved for commercial release south of latitude 22° South in Australia in 2002 (DIR 012/2002).

GTTAC discussed this application from Bayer CropScience and advised the Regulator that:

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

[1] Enzymes are proteins which catalyse specific biochemical reactions.

Advice on Mustard

- **DIR 57/2004 Field trial - Gene Technology Modified Herbicide Tolerant Hybrid Indian Mustard**

The OGTR prepared a RARMP for a licence application proposing the intentional release of GM *Brassica juncea* (Indian mustard) into the environment on a limited scale and under controlled conditions. The GM mustard lines proposed for release have been genetically modified by the introduction of genes for herbicide tolerance and a hybrid breeding system. The trial is proposed to take place on up to a total of 96 hectares over three years during the winter and summer growing seasons of 2005-08. Sites will be chosen from 17 shires in Victoria, South Australia and New South Wales.

The main aims of the proposed trial are to evaluate the effectiveness of the herbicide tolerance trait in the field, to observe the agronomic performance of the GM mustard lines and to increase seed.

GTTAC considered the draft RARMP for this application and advised the Regulator that:

- although not necessary to manage risks associated with this release, information on agronomic performance should be recorded during the release;
- the risk assessment identifies all the risks associated with the proposed dealings; and
- the measures proposed in the risk management plan are adequate to deal with the identified risks.

Advice on Applications

Advice on Cotton

- **Commercial release of Roundup Ready Flex cotton MON88913 (DIR 059/2005)**

The OGTR has received an application from Monsanto Australia Ltd for a commercial release of genetically modified (GM) Roundup Ready Flex® cotton in the cotton growing areas south of latitude 22° South in Australia and for small scale plantings in other areas south of latitude 22° South for evaluation trial and demonstration, education and research purposes.

Roundup Ready Flex® cotton differs from the previous commercially released Roundup Ready® cotton in that tolerance to Roundup Ready® herbicide is prolonged. Currently, if Roundup Ready® herbicide is applied to Roundup Ready® cotton after the four leaf growth stage, the cotton plants would be susceptible to the herbicide. Cottons containing the Roundup Ready Flex® trait are able to tolerate application of Roundup Ready® herbicide at later stages of plant growth without yield loss, allowing a wider window to apply herbicide during growth of the cotton crop. This is intended to give growers increased flexibility in timing of herbicide use for weed management. An application has also been submitted by Monsanto to Australian Pesticides and Veterinary Medicines Authority to allow the use of Roundup on GM cotton beyond the 4-leaf stage.

GTTAC discussed this application and advised the Regulator that the risks associated with toxicity, allergenicity, weediness and gene flow in relation to commercial scale release of Roundup Ready Flex® should be considered in the RARMP.

Advice on Rose

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

The OGTR has received a licence application from Florigene Ltd (Florigene) for the limited and controlled release of genetically modified (GM) coloured rose. The three GM rose lines proposed for release have been genetically modified by insertion of genes which will affect the colour of the rose flowers. The GM rose lines are of hybrid tea and floribunda varieties.

The aims of the proposed release are to: enable evaluation of the imported GM rose lines in a semi-contained Australian facility; conduct limited propagation; and provide data to support a future application for commercial release. The GM rose lines would be grown in pots in a greenhouse. About 100 plants of each GM rose line are proposed for release, along with about 100 each of the two non-GM plants parental rose varieties.

The trial is proposed to be conducted within a free standing greenhouse of framed heavy duty plastic, with a soil floor. The GM roses will be grown in pots using a hydroponic system above soil level.

There has been no previous release of these GM rose lines in Australia. However, under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC) two field trials by Calgene Pacific Pty Ltd (now Florigene) of GM roses with modified flower colour were approved (PR 30 and PR 35).

GTTAC discussed this application from Florigene and advised the Regulator that:

- proposed methods of disposal should be more clearly defined by the applicant;
- mulching and composting the GM material as a method of disposal would be sufficient and the compost should be monitored after six months to check for regrowth;
- further information should be sought from the applicant regarding the security of the greenhouses. GTTAC recommended that the greenhouses should be locked;
- further information should be sought from the applicant regarding whether the GM roses would be grown on rootstock, and if so what type of rootstock would be used; and
- details of the AQIS import permit held by Florigene for the import of the GM roses should be clarified.

Advice on Carnation

- **Request to place GM carnations on the GMO Register (Reg 001/2004)**

The OGTR has received an application from Florigene Ltd (Florigene) to place GM carnations on the GMO Register. This is the first application that the Regulator has received to include dealings with a GMO on the GMO Register.

Section 79 of the *Gene Technology Act 2000* sets out matters the Regulator must take into account when considering whether dealings with a GMO may be included in the GMO Register:

- The Regulator must be satisfied that any risks posed by the dealings with the GMO are minimal. This matter has been addressed in the RARMP for licence application DIR 030/2002 from Florigene. All risks considered in this RARMP were assessed as negligible. If new information is identified that warrants updating the RARMP, then the RARMP for DIR 030/2002 will be updated to incorporate the new information and risks associated with the proposed dealings will be reassessed.

- The Regulator must also have regard to any available data on adverse effects posed by the dealings and any other information on risks associated with the dealings. The licence holder estimates that 150,000-200,000 GM carnations have been grown and sold within Australia up to September 2004 and approximately 5.5 million GM carnations have been produced in the USA, Japan, Eucador and Colombia. Annual reports provided by the licence holder state that no unintended or adverse effects have been reported and no additional risks associated with dealing with the GMOs have been identified.

- The Regulator must also consider whether there is a need for the dealings to be subject to conditions. Specific conditions in licence DIR 030/2002 included a condition that testing methods for identifying the GMOs be provided to the Regulator. These methods have since been supplied. In addition, the licence holders were required to report any adverse effects caused as a result of the GMOs and keep written records of contact details for all persons contracted to propagate and grow the GMOs, the locations at which GMOs were propagated and grown and the total number of GMOs propagated and grown. These records were included in the organisation's annual report to the Regulator.

Before a GMO can be considered for listing on the GMO Register it must have been licensed by the Regulator. A determination by the Regulator that a dealing be placed on the GMO Register is a disallowable instrument and must be tabled in the Australian Parliament.

The dealings that Florigene propose for inclusion on the GMO Register are those dealings that have previously been authorised under DIR licence DIR030/2002. In brief the proposed dealings are for an ongoing, Australia-wide commercial release of carnations genetically modified for blue flower colour.

GTTAC considered the current RARMP that was prepared for the commercial release of GM carnations (DIR 030/2002) and advised the Regulator that:

- the RARMP identifies all of the risks posed by the proposal to list GM carnations on the GMO Register; and

- the risks are negligible and dealings with GM carnations are suitable for inclusion on the GMO Register.

Other Advice

- **DNIR 298/2004 - VARIATION: Phase I/IIA, Two centre, open-label, dose escalation study to assess the safety, tolerability and efficacy of FP253 in combination with fludarabine phosphate**

GTTAC previously considered the DNIR licence application for this dealing which involves a human clinical trial. The applicant has subsequently submitted an application to vary the licence and the Regulator sought GTTAC advice on the proposed licence variation.

GTTAC considered the application and advised the Regulator on containment and safety issues.

- **DNIR 366/2005 - Phase III clinical trials of ChimeriVax™-JE**

An application has been submitted to the OGTR to conduct phase III clinical trials of the ChimeriVax™-JE vaccine. ChimeriVax-JE™ has previously been considered by the OGTR for phase II clinical trials (DNIR 319/2004, 320/2004).

GTTAC considered the application and advised the Regulator that the risk assessment prepared for phase II clinical trials identifies all risks associated with the phase III trial.

Presentations

The following presentations were made to GTTAC:

- Overview of the work conducted by the Monitoring and Compliance Section at OGTR;
- Introduction to the format for revised Risk Assessment and Risk Management Plans (RARMP) to be used for DIR licence applications in line with the revised Risk analysis Framework; and
- Feedback from the inaugural national Institutional Biosafety Committee Forum that was held in Canberra in April 2005.

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