
Gene Technology Technical Advisory Committee

**COMMUNIQUE
No. 18**

This is the eighteenth communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty-eighth meeting of GTTAC, held on 19 September 2006 and out-of-Session items considered in July and August 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 Risk Assessment and Risk Management Plans (RARMPs) that are prepared for 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 Applications

DIR069/2006 – Field trial of GM herbicide tolerant GM hybrid *Brassica napus* and hybrid *Brassica juncea* lines

GTTAC considered an application from BayerCropScience Pty Ltd for the intentional release of GM herbicide tolerant, hybrid *Brassica napus* (canola) and *Brassica juncea* (Indian mustard) lines into the environment on a limited scale and under controlled conditions. The proposed release would take place at up to 42 sites over four years (2007-2010), with a maximum area of less than 300 hectares in New South Wales, Victoria and South Australia.

The aim of the proposed trial is to produce seed and to evaluate agronomic traits such as herbicide tolerance, germination and flowering dates of the GM canola and Indian mustard lines under Australian cropping systems.

The Committee suggested that additional information should be provided on the trial protocols and literature review.

GTTAC indicated that any movement of introduced genetic material was only likely to occur at very low levels and that herbicide tolerance was unlikely to increase the weediness of either the GM canola or Indian mustard.

DIR 067/2006 – Limited and Controlled Release of GM cotton lines with tolerance to waterlogging stress

GTTAC was asked to provide out-of-session advice in August 2006 on an application from CSIRO seeking approval for a limited and controlled release of up to 30 cotton lines that have been genetically modified to provide tolerance to waterlogging stress. The release is proposed to take place at one site in the shire of Narrabri, NSW on a maximum total area of 0.1 ha during each of the three summer growing seasons between September 2006 and May 2009.

The purpose of the release is early stage research to measure the levels of expression of the waterlogging tolerance gene and to assess the effectiveness of the protein it produces under simulated waterlogged conditions. In addition, the agronomic performance of the GM cotton lines will be compared to that of

non-GM cotton and some seed will be collected for testing or possible future trials (subject to additional applications and assessments).

GTTAC advised that the Regulator should consider toxicity, allergenicity, increased weediness and proposed containment measures.

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

GTTAC was asked to provide out-of-session advice in August 2006 on an application from Florigene Pty Ltd seeking approval for a limited and controlled release of nine torenia lines that have been genetically modified to produce a range of flower colours. A field trial with up to 200 plants is proposed at one site of approximately 100m² during the summer of 2007/08. The GM plants will be grown in hanging baskets suspended above a concrete or gravel surface.

The purpose of the release is to evaluate the performance of the GM torenia lines by measuring the expression of the introduced genes, horticultural characteristics such as plant size, number and longevity of flowers, flower colour stability and susceptibility to pests and diseases.

GTTAC advised that the Regulator should consider toxicity, allergenicity, increased weediness and proposed containment measures.

DIR 070/2006 – Limited and controlled release of GM sugarcane for altered shoot architecture, drought tolerance and nitrogen efficiency

GTTAC was asked to provide out-of-session advice in August 2006 on an application from Bureau of Sugar Experiment Stations Limited seeking approval for a limited and controlled release of twenty two sugarcane lines. The GM sugar cane lines have been genetically modified to produce altered shoot architecture, increased drought tolerance and increased nitrogen use efficiency. A field trial with up to 2500 lines derived from 22 gene constructs is proposed at three sites of approximately 2 hectares each from March 2007 to November 2010.

The purpose of the release is to evaluate the performance of the GM sugarcane lines by measuring the horticultural characteristics including sugar yields, plant size, number and length of tillers, drought tolerance, and nitrogen use efficiency.

GTTAC advised that the Regulator should consider toxicity, allergenicity, increased weediness and proposed containment measures.

Advice on RARMPs

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

Advice on GM Cotton

DIR 064/2006 – Limited and controlled release of GM water-efficient cotton

GTTAC considered the RARMP for licence application DIR064/2006 received from Monsanto Australia Ltd to carry out a small scale field trial of GM cotton lines on up to 10 sites per season in New South Wales and/or Queensland covering an area of up to 20 hectares each season for two summer growing seasons in 2006/07 and 2007/08. Each site would be no more than 2 hectares in size.

The purpose of the proposed trial is to conduct 'proof of concept' research to assess the agronomic characteristics of the GM cotton lines in the field including water use efficiency, yield and fibre quality under different irrigation treatments. Seed would be collected for further studies and possible future releases of lines selected for further development (subject to additional applications and approvals).

Each GM cotton line contains 1 of 24 introduced genes encoding proteins believed to enhance the water use efficiency of cotton. Twenty three of the genes are derived from the plants *Arabidopsis thaliana* (thale cress), *Zea mays* (maize), *Glycine max* (soybean), *Oryza sativa* (rice) and *Gossypium hirsutum* L. (cotton). One gene is derived from the bacterium *Escherichia coli*.

There have been no previous releases of these GM cotton lines in Australia.

In addition to providing comments on the adequacy of the hazard identification, risk assessment and licence conditions, GTTAC was asked to consider any risks which may or may not arise from potential asynchronous or altered flowering patterns arising from the genetic modification.

GTTAC advised that information on possible altered flowering patterns might be collected during that trial. GTTAC also suggested that information be sought on the proximity of the proposed trial site to commercial seed production sites.

GTTAC agreed with the risk assessment and that the proposed licence conditions were adequate to contain the release to the locations, size and duration of the trial.

DIR 065/2006 – Limited and controlled release of GM insect resistant (VIP3A and/or Cry1Ab) cotton

GTTAC considered a RARMP for licence application DIR065/2006 from Deltapine Australia Pty Ltd seeking approval to conduct a small scale field trial of up to 11 lines of insect resistant cotton at one site of 1.5 hectares in the shire of Narrabri in NSW, over one season (summer 2006/07). The purpose of the trial is to conduct early stage research to produce seed from the GM cotton lines for use in further studies in future trials (subject to further applications and approvals). The applicant also proposed selling lint from the release.

The Committee considered the proximity of bee hives to trial sites and accepted that isolation zones were similar to those applied in previous licences.

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 proposed location, size and duration requested by the applicant.

DIR 066/2006 – Commercial release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22° South

GTTAC considered a RARMP for licence application DIR066/2006 from Monsanto Australia Ltd seeking approval to release GM cotton, without specific containment measures, north of latitude 22° South.

The five types of GM cottons have all been previously approved for commercial release in northern Australia. They comprise:

- insect resistant Bollgard II[®] cotton (also known as MON15985)
- herbicide tolerant Roundup Ready[®] cotton (also known as MON1445)
- herbicide tolerant Roundup Ready Flex[®] cotton (also known as MON88913)
- herbicide tolerant/insect resistant Roundup Ready[®]/Bollgard II[®] cotton (also known as MON1445/MON15985)
- herbicide tolerant/insect resistant Roundup Ready Flex[®]/Bollgard II[®] cotton (also known as MON88913/MON15985).

The committee indicated its agreement with the conclusion of the RARMP. GTTAC noted its satisfaction which enables the risk of increased weediness in northern Australia as a result of insect resistance to be assessed as negligible,

DIR 067/2006 – Limited and controlled release of waterlogging tolerant GM cotton

GTTAC considered a RARMP for licence application DIR067/2006 from CSIRO Plant Industry to conduct a small scale field trial of up to 30 lines of waterlogging tolerant GM cotton on a 0.1 ha at one site in the shire of Narrabri, NSW, during three summer growing seasons (2006/07, 2007/08, 2008/09).

The purpose of the proposed release is to conduct 'proof of concept' research to measure the expression levels of the *AHb1* gene; to evaluate the tolerance of the GM cotton plants to waterlogging stress under simulated conditions; and to assess their agronomic performance in the field.

Cotton seed will also be collected for further studies and possible future releases (subject to additional applications and approvals). No products from the release would be used for human food, animal feed or for the production of fabrics and/or other cotton products.

The Committee discussed the RARMP and members agreed that the risk assessment identifies all risks associated with the release. The Committee also believed that the proposed licence conditions, which are based on previous licences, for the release of this GM cotton are adequate to contain the release to the location, size and duration of the trial.

DIR 062/2005 – Commercial Release of Herbicide Tolerant Liberty Link[®] Cotton for use in the Australian Cropping System

Advice was sought from GTTAC out-of-session July 2006 on a RARMP for licence application DIR062/2005 from Bayer CropScience seeking approval to commercially release herbicide tolerant Liberty Link[®] Cotton without specific containment measures. The applicant indicated that, if approval was received, growing of GM cotton would occur initially in the existing cotton growing regions of New South Wales and Queensland, followed by uptake in other areas where environmental conditions are suitable for cotton cultivation.

Bayer does not propose to use any containment measures and intends that the GM cotton plants and their products would be used in the same manner as conventional and other commercially approved GM cottons. The dealings would include use in human food, conventional breeding with non-GM cotton varieties, sale of seed and lint and exporting seed and could involve transportation and use of cotton seed as stockfeed anywhere in Australia.

GTTAC indicated agreement with the conclusions of the RARMP ie and advised the Regulator that the proposed commercial release of Liberty Link[®] Cotton poses negligible risks to the health and safety of people and the environment as a result of gene technology and that specific risk treatments measures are not required.

DIR 063/2005 – GM Cotton Field Trial – Assessment of transgenic cotton (*Gossypium Hirsutum*) expressing natural plant genes for fungal control

Advice was sought from GTTAC out-of-session in July 2006 on a RARMP for licence application DIR063/2005 from Hexima Limited seeking approval to carry out a small scale field of one GM cotton line on two sites in the Pittsworth Shire (Queensland), and one site in the Narrabri or Moree Plains Shires (New South Wales), covering an area of up to 1.0 hectare each season during each of three growing seasons between 2006 and 2009.

The GM cotton line contains a fungal resistance gene (*nad1*) encoding a plant defensin protein which is expected to enhance resistance against major fungal diseases of cotton, including Fusarium wilt, black root rot and Verticillium wilt.

GTTAC advised the Regulator that the Committee agreed with the risk assessment and that the proposed licence conditions were sufficient to contain the release to the locations, size and duration proposed 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.

The OGTR sought GTTAC advice on the following DNIR application and RARMP in an out-of-session package in July 2006.

DNIR 396/2006 – Clinical Trial of ChimeriVax™- DEN

Advice was sought from GTTAC out-of-session in July 2006 on an application from Institute of Drug Technology Australia Limited to conduct a Phase IIa clinical trial (CYD10) of ChimeriVax™-DEN, a tetravalent, live, attenuated, chimeric, genetically modified vaccine against *Dengue* virus (DV).

The protocol proposed in the dealing has been approved the Therapeutic Goods Administration clinical trial exemption (CTX) scheme and the Gene and Related Therapies Research Advisory Panel (GTRAP) at the NHMRC, including an evaluation by GTRAP of the risks to the volunteers receiving the vaccine.

GTTAC considered the application and RARMP for DNIR386/2006 and advised the Regulator that the risk assessment prepared for Phase II clinical trial identified all risks associated with the Phase II trial.

Presentations

The following presentations were made to GTTAC:

- legal issues relating to the release of information held by the OGTR;
- update on the review of the Gene Technology Regulations 2001; and
- an update on the revision of Certified Contained Facilities Guidelines.

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>.