
Gene Technology Technical Advisory Committee

Communiqué No.17

This is the seventeenth Communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty-seventh meeting of GTTAC, held on 29 March 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 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 (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 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 Wheat

DIR 061/2005 – Field testing of genetically modified salt tolerant wheat on saline land

Grain Biotech Australia Pty Ltd has submitted an application for a licence for a small scale field trial 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 an area of 0.45 hectares.

Under the proposed trial, the wheat lines will be planted in soil with a salinity gradient and evaluated for salt tolerance and agronomic performance.

The GM wheat lines have been modified to contain one or more copies of the ornithine aminotransferase (*oat*) gene, which is derived from the common plant *Arabidopsis thaliana*. The *oat* gene leads to increased production of proline, an osmoprotectant, which is a molecule that can protect plant proteins and membranes against 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 advised the Regulator that:

- GTTAC agrees with the assessment made by the OGTR;

- GTTAC agrees with the proposed licence conditions except that monitoring should be continued for 12 months after the last volunteer, rather than a non-qualified 2 years;
- It should be clarified that livestock would not have access to the site until after the monitoring period;
- Containment measures proposed by the applicant should be distinguished from the licence conditions proposed by the Regulator; and
- The risk assessment identifies all the events by which the proposed release could potentially give rise to adverse outcomes to the health and safety of people or the environment posed by or as a result of gene technology.

Advice on Applications

Advice on GM Cotton

Commercial Release of Herbicide Tolerant Liberty Link® Cotton for use in the Australian Cropping System

(DIR 062/2005)

Bayer CropScience (Bayer) has submitted an application seeking approval to commercially release GM herbicide tolerant Liberty Link® Cotton in Australia. Bayer has predicted that the most substantial adoption of the GM cotton will 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.

Liberty Link® Cotton contains the *bar* gene which confers tolerance to glufosinate ammonium, the active ingredient in several herbicides including Liberty®. Liberty Link® Cotton can be sprayed with glufosinate ammonium to kill weeds without damaging the crop itself.

Bayer proposes that the GM cotton plants and their products be used in the same manner as conventional and other commercially approved GM cottons – which includes use in human food and stockfeed, transportation, sale of lint and exporting seed.

Liberty Link® Cotton was previously assessed under DIR 056/2004.

GTTAC advised the Regulator that the following issues should be considered in preparation of the RARMP:

- The impact of removing all containment measures;
- Specific issues relating to the unrestricted use of the GM cotton in northern areas of Australia including planting, stock feeding and transportation; and

- Specific issues relating to consequences of stacking with other commercially released GM cottons.

In addition GTTAC recommended that advice provided in relation to previous assessments of this GM cotton and other herbicide tolerant GM cottons should be considered when drafting the RARMP.

**Field trial of GM cotton (*Gossypium hirsutum*) expressing natural plant genes for fungal control
(DIR 063/2005)**

The Regulator has received an application from Hexima Limited which proposes a small scale field trial of GM Cotton lines on two sites in the Pittsworth Shire, Queensland, and one site in the Narrabri or Moree Plains Shire, New South Wales. The trial would cover an area of up to one hectare per season for three growing seasons from 2006 to 2009.

The GM cotton lines contain the commonly used antibiotic resistance gene neomycin phosphotransferase (*nptII*) gene and a fungal resistance gene (*NaD1*). The *NaD1* gene encodes a plant defensin protein which enhances resistance to major fungal diseases of cotton, including Fusarium wilt, black root rot and Verticillium wilt.

The aims of the proposed limited and controlled release are to: evaluate the three GM cotton lines for enhanced resistance to fungal diseases compared with non-GM cotton lines; assess agronomic performance under field conditions; measure the expression levels of the defensin protein; and test for adverse impacts on selected beneficial microorganisms (mycorrhiza).

No products from the release would be used for human food or animal feed.

GTTAC advises the Regulator that the following issues should be assessed in the RARMP:

- Potential for toxicity/allergenicity of NAD1 proteins in the GM cotton line to humans and other organisms including beneficial soil microorganisms; and
- Potential for the GM cotton lines to be harmful to the environment arising from potential for increased weediness.

**GM Cotton Field Trial – Limited and controlled release of water efficient GM cotton
(DIR 064/2006)**

Monsanto Australia Limited has applied for approval for a limited and controlled release of GM cotton lines which have been modified for increased water efficiency.

Up to 24 GM cotton lines are proposed for release in 10 sites in New South Wales. Each line contains 1 of 24 different genes derived from the plants *Arabidopsis thaliana* (thale cress), *Zea mays* (corn), *Glycine max* (soybean), *Oryza sativa* (rice) and *Gossypium hirsutum* (cotton). The introduced genes encode proteins that are intended to confer enhanced water use efficiency by regulating expression of endogenous genes or modulating biochemical pathways in the cotton plants.

The purpose of the trial is to evaluate the agronomic characteristics, water use efficiency, yield and fibre quality of the GM cotton lines under optimum watering and water stress treatments. Seed will be collected for further studies including possible future releases (subject to additional assessments and approvals).

Aspects of the genetic modification are pending a decision for an application to declare them confidential commercial information, but were made available to GTTAC.

GTTAC advised the Regulator that:

- The potential for toxicity/allergenicity of the GM cotton lines to humans and other organisms should be assessed; and
- The potential for the GM cotton to be harmful to the environment because of an increased potential for weediness should be assessed.

GM Cotton Field Trial – Limited and controlled release of GM insect resistant (*VIP3A* and/or *Cry1Ab*) Cotton

(DIR 065/2006)

Deltapine Australia Pty Ltd is seeking approval for a small scale field trial of GM cotton (*Gossypium hirsutum* L). The trial proposes using 11 GM cotton lines, containing one or two insect resistance genes (*vip3A* and/or *cry1Ab*). These insect resistant genes are toxic to the major lepidopteran caterpillar pests of cotton.

The aim of the trial is to produce seed for future GM cotton trials and Deltapine proposes to conduct the trial at a site in Narrabri, New South Wales.

These insect resistance genes have been involved in previous limited releases on an individual basis. This is the first time that the combination of these two genes will be assessed.

GTTAC advised the Regulator that:

- The potential for toxicity/allergenicity of the GM cotton lines to human be assessed;
- The potential for toxicity for the GM cotton lines to non-target organisms, including predators of the target pests, be assessed; and
- The potential for the GM cotton lines to be harmful to the environment because of an increased potential for weediness be assessed.

Commercial release of GM herbicide tolerant and/or insect resistant cottons north of latitude 22° South

(DIR 066/2006)

Monsanto Australia Limited has applied for approval of the general release of five types of herbicide tolerant and/or insect resistant GM cotton lines north of latitude 22° South.

The five types of GM cottons are:

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

Bollgard II[®] cotton contains two insecticidal genes (*cry1Ac* and *cry2Ab*), which confer resistance to the major lepidopteran caterpillar pests of cotton. Roundup Ready[®] cotton contains one copy of the *cps4 epsps* gene conferring tolerance to glyphosate up to the four-leaf stage of growth. Roundup Ready Flex[®] cotton contains two copies of the *cps4 epsps* gene, which confers tolerance to glyphosate throughout the growing season. The stacked GM cottons (Roundup Ready[®]/Bollgard II[®] and Roundup Ready Flex[®]/Bollgard II[®]) contain all the genes introduced into each of the parent GMOs.

The applicant has proposed that the GM cotton be used in the same manner as conventional and other commercially approved GM cottons. This includes use in human food and stockfeed, transportation, sale of lint and export of seed.

GTTAC advised the Regulator that:

- The impact of unrestricted dealings with the GM cottons in northern areas of Australia including planting, stock feeding and transportation should be assessed;
- The impact of removing all containment measures should be assessed; and
- The impact of stacking these cottons with GM Liberty Link[®] Cotton (tolerant to glufosinate ammonium) which is currently subject to assessment (DIR 62/2005) should be assessed.

Other Advice

DNIR 275/2004 – VARIATION: Viral protein gene function in whole virus for screening anti-viral compounds

Biotron is a biotechnology company currently conducting research into the development of novel antiviral therapeutic agents. To facilitate the screening and identification of antiviral agents, Biotron applied for, and was granted a DNIR licence permitting the construction of live viruses with a range of specific genetic modifications. Aspects of this licence, including the specifics of the genetic modifications are protected by a declaration of confidential commercial information (CCI).

In order to further this research, Biotron has requested a variation to their licence to broaden the source of genetic material used for the genetic modifications and alter their methodology. The specifics of this variation are also covered by a CCI declaration but were made fully available to GTTAC.

GTTAC advised the Regulator that:

- The variation as proposed may pose increased risks that would not be managed by the original risk assessment and risk management plan;
- Work involving GM viruses in which the proposed modifications have been carried out *in trans* may require Physical Containment Level PC 2 to adequately manage the risks to human health and the environment; and
- Work involving GM viruses in which the proposed modifications have been carried out *in cis* may require PC 3 to adequately manage the risks to human health and the environment.

Presentations

The following presentations were made to GTTAC:

- Overview of the GeneAEx software package, which is used to analyse population genetics data.
- Information about morpholino oligos, which are key molecules in an antisense technology being used in emerging therapies for sufferers of Duchenne Muscular Dystrophy.
- An overview of the developments in the *National Framework for the Development of Ethical Principles in Gene Technology*, which is being produced by the Gene Technology Ethics Committee.

Review of the Gene Technology Regulations 2001 (the Regulations)

GTTAC was provided with an update on the Review of the Regulations. A representative of the OGTR outlined changes which had been made to the Amendment Regulations since the previous GTTAC meeting, and the timeframes and processes outstanding for the finalisation of the draft amendments.

A number of members attended a meeting on 17 January 2006 to discuss the Review of the Regulations with the OGTR. A report was given to the full Committee detailing the outcomes of this meeting.

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 the OGTR website at <http://www.ogtr.gov.au>