# GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

# COMMUNIQUE
# No. 14

***This is the fourteenth communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty third meeting of GTTAC, held on 7 & 8 March 2005 and at a teleconference on 31 May 2005 as well as matters considered by GTTAC out-of-session in January 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 Communique 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 Communique 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 Bovine herpesvirus vaccine

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

- **Vaccine trial – vaccination of cattle with recombinant *Bovine herpesvirus* vaccines (DIR 050/2004)**

The OGTR has received an application from the Queensland Government Department of Primary Industries and Fisheries (QDPIF) for the limited and controlled release of up to 19 genetically modified (GM) *Bovine herpesvirus* (BoHV-1) vaccines into the environment. The aim of the trial is to evaluate the safety and efficacy of the GM vaccines to protect cattle from primary infection from BoHV-1 and *Bovine viral diarrhoea virus* (BVDV).

The trial will be conducted in Queensland and will involve the inoculation of up to 180 cattle, aged between 4 to 6 months with the approved GM vaccines administered via a nasal drip. Groups of cattle will be inoculated with the GM vaccines and held in the PC1 animal containment facility for 6-8 weeks. During this time their immune response to the vaccines will be tested. The cattle will shed GM virus for up to 8 days following inoculation and after that time they will be latently infected with the GMOs.

At the end of the test period the cattle will be euthanased in a post-mortem room on site except for 1 or 2 of the groups of cattle that will be moved from the PC1 animal containment facility to designated paddocks on site for a period of 3 weeks before being euthanased.

The GM vaccines will be produced by the insertion of one or more of 19 gene constructs that encode either of the envelope (E) glycoproteins[1] E0 and E2 from BVDV into an existing, conventional BoHV-1 vaccine strain V155. This existing vaccine has been used in over 2 million feedlot cattle with no adverse effects to human health and safety or to the environment being recorded.

While there have been no previous releases of these GM vaccines in Australia, a field trial with a similar vaccine was conducted under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC). There have been no reports of adverse effects on human health or the environment resulting from this release.

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

- the Committee agrees with the assessment made by the OGTR on risk of toxicity, allergenicity and transmission of the GMOs;
- the risk assessment identifies all risks associated with the release; and
- the Committee agrees with the proposed licence conditions and recommends the use of sentinel sheep.

[1] *Envelope glycoprotein* - a glycosylated protein that is located in the envelope of a virus and that is capable of stimulating an immune response.

## Advice on GM Wheat

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

- **Field trial of genetically modified salt tolerant wheat on saline land (DIR 053/2004)**

The OGTR has received an application from Grain Biotech Australia to carry out a small scale field trial of GM wheat on a single site in the Corrigin Shire, Western Australia, covering an area of up to 0.45 hectares from April 2005 to January 2006.

The aim of the proposed release is to evaluate tolerance to saline soil and to evaluate agronomic performance of the GM wheats under Australian field conditions.

The GM salt tolerant wheat has been genetically modified to contain the ornithine amino transferase gene *(oat)* isolated from *Arabidopsis thaliana*. The *oat* gene produces the enzyme, ornithine amino transferase enzyme (OAT). Over-expression of this enzyme can increase proline levels in the plant. The GM wheat also contains the selective marker gene, cyanamide hydratase (*cah*) isolated from the soil fungus *Myrothecium verrucaria*. The *cah* gene produces the enzyme cyanamide hydratase (CAH) that confers cyanamide resistance by hydrating the nitrile group of cyanamide to produce urea.

The proposed release would consist of the GM wheat, non-GM bread wheat, a non-GM barley, a non-GM durum wheat and non-GM salt adapted bread wheat.

None of the GM wheat and pollen trap plants from the trial, or their by-products will be used for human food or animal feed.

There have been no previous releases of the proposed GM wheats. However, five field releases of other GM wheats were approved under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC).

GTTAC discussed this application from Grain Biotech Australia and advised the Regulator that:

- the risk assessment identifies all risks associated with the release;
- the terminology used in the RARMP to describe allergenicity, toxicity and the risk management of rodents and birds should be adjusted; and
- the Committee agrees with the proposed licence conditions and recommended the use of bird netting on the proposed trial site.

- **Field trial of genetically modified wheat with altered grain starch (DIR 054/2004)**

The OGTR has received an application from CSIRO Plant Industry (CSIRO) for a licence to allow the intentional release of genetically modified (GM) wheat into the environment on a limited scale and under controlled conditions. The release is proposed to take place at one site covering a maximum total area of 0.25 ha in the Australian Capital Territory (ACT) from May 2005 to December 2006.

The GM wheats proposed for release have been genetically modified with a gene silencing construct designed to prevent the expression of either starch enzymes (SE) I or II which

influence starch metabolism in wheat. The SE sequences in the silencing constructs and the high molecular weight (HMW) glutenin promoter (endosperm specific) were both derived from wheat. The effect of the gene silencing is to increase the proportion of amylose as opposed to amylopectin stored in the wheat grain. The transformation construct also contains the neomycin phosphotransferase (*nptII*) gene, derived from *Escherichia coli*, as a selectable marker.

CSIRO has sought and received approval to have details of the gene constructs, sequence information and precise identification of the genes involved declared as confidential commercial information (CCI).

The aim of the proposed release is to assess the field performance of GM wheat with altered starch characteristics and to generate seed stocks of the wheat lines for future research.

None of the material harvested from the trial will be used for human food or stock feed and any material not used for further research will be destroyed. This GM wheat would require approval by Food Standards Australia New Zealand (FSANZ) before it could be used for human consumption.

There have been no previous releases of the proposed GMO under the Gene Technology Act 2000. However, five field releases of other GM wheats were approved under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC).

GTTAC discussed this application from CSIRO Plant Industry and advised the Regulator that:

- the Committee agrees with the assessment made by the OGTR on risk of toxicity, allergenicity, weediness and gene transfer;
- the risk assessment identifies all risks associated with the release; and
- the Committee agrees with the proposed licence conditions and recommends that the monitoring should be carried out for a period of 24 months.

## Advice on Cotton

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

- **Field trial of herbicide tolerant (Roundup Ready® Flex MON 88913) and herbicide tolerant/insect resistant (Roundup Ready® Flex MON 88913/Bollgard II®) cotton (DIR 055/2004)**

Monsanto proposes to conduct a field trial on 91 sites covering a maximum total area of 1811 hectares, over two planting seasons, the southern summer growing season and the northern winter growing season, between September 2005 and November 2006. The summer trial sites (maximum of 1767 hectares) would be in the cotton growing regions of New South Wales and southern Queensland, and the winter trial sites (maximum of 42 hectares) would be in northern Western Australia, the Northern Territory and northern Queensland.

The aims of the proposed release are to:

- transfer the Roundup Ready® Flex herbicide tolerant trait into elite cotton varieties suitable for use under Australian conditions;

- test agronomic performance including disease resistance (bacterial blight and fusarium and verticillium wilts);

- produce seed for future releases (which would require separate applications and approval processes);

- set up demonstration sites for industry, government, researchers and the wider community; and

- collect data required for future applications to the OGTR and other regulators for commercial release such as levels of novel protein expression and seed composition (required by the OGTR and Food Standards Australia New Zealand (FSANZ)) and data on the GM cottons' tolerance to glyphosate, weed control effectiveness and glyphosate residue levels (required by the Australian Pesticides and Veterinary Medicines Authority).

Roundup Ready® Flex MON 88913 cotton, contains two copies of a gene, *cp4 epsps*, derived from *Agrobacterium* sp. strain CP4, conferring tolerance to glyphosate, the active ingredient in Roundup® herbicides. The proposed release will also include some lines containing the RR Flex trait in combination with Bollgard II® cotton (containing two insecticidal genes, a reporter gene and an antibiotic resistance marker gene).

It was noted that GTTAC had considered and provided advice on this proposal at its previous meeting on 21 September 2004 and that the risks posed under this proposal are similar to those for DIRs 005, 006, 009, 012, 023 and 035.

Details of the gene construct, including the plasmid map and some of the regulatory sequences have previously been declared as Confidential Commercial Information (CCI) under section 185 of the Act, in connection with licence application DIR 035/2003.

GTTAC discussed this application from Monsanto Australia Ltd and advised the Regulator that:

- the Committee agrees with the assessment made by the OGTR on risk of toxicity, allergenicity and gene transfer;

- the terminology in the RARMP should be reviewed to ensure the clear differentiation of hazards and risks;

- the risk assessment identifies all risks associated with the release;

- the RARMP should address the risk of visitors to the site accidentally removing material from the trial site; and

- the Committee agrees with the proposed licence conditions.

## Advice on Applications

## Advice on Indian Mustard

- **Field trial to allow controlled release of genetically modified, herbicide tolerant hybrid Indian Mustard (*Brassica juncea*) (DIR 057/2004)**

The OGTR has received an application from Bayer CropScience Pty Ltd (Bayer) for a licence to allow the intentional release of GM Indian mustard (*Brassica juncea*) into the environment on a limited scale and under controlled conditions. The proposed release would take place at four sites each in the winter and summer growing seasons of 2005-2008, on a maximum area of four hectares per site, in up to 17 shires in New South Wales, South Australia and Victoria.

The main aims of the proposed release are to: evaluate the effectiveness of the introduced herbicide tolerance trait in the field; assess the agronomic performance of GM Indian mustard lines in Australia, including comparisons with GM and conventional canola and conventional Indian mustard; and to produce seed for further evaluation overseas and in Australia.

The GM Indian mustard incorporates the barnase-barstar hybrid breeding system and a herbicide tolerance gene. Both these traits in canola (*Brassica napus*) were approved in 2004 for field trials under licence DIR 032/2002. The GM Indian mustard proposed for release has been derived by conventional breeding conducted overseas between GM canola approved under licence DIR 032/2002 and Indian mustard. The F1 hybrid was then further backcrossed to Indian mustard. The barnase-barstar hybrid breeding system is also present in InVigor® canola approved for commercial release under licence DIR 021/2002.

The *barnase* (male sterility) and *barstar* (fertility restorer) genes are derived from the bacterium *Bacillus amyloliquefaciens*. Bayer sought and received approval to have information relating to the introduced herbicide tolerance gene, regulatory elements, gene constructs including plasmid maps, precise arrangement of the genetic elements and data on molecular characterisation of the GM Indian mustard (derived from the GM canola under licence DIR 032/2002) declared as Confidential Commercial Information (CCI).

None of the GM *B. juncea* plants from the release, or their by-products would be used for stock feed or human food. An approval from FSANZ would be required before oil from the GM *B. juncea* lines could be used for human consumption.

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

- The Committee would like further information from the applicant concerning the location, containment and fate of bees;
- The Committee recommended a more structured representation of the trial objectives
- A GTTAC working group was established to consider further information provided by the applicant regarding bees and weediness for preparation of the RARMP.

## Other Advice

- DIR 051/2004 – Field trial of sugarcane expressing sucrose isomerase (University of Queensland); and

- DIR 052/2004 - Phenotyping of T-DNA and/or transposon Ds insertion line of rice (*Oryza sativa* L) under field conditions (CSIRO).

The OGTR sought GTTAC advice on RARMPs for the above DIR applications in an out of session package in January 2005 due to legislative time constraints which prevented their consideration at the 7/8 March 2005 GTTAC meeting.

These DIR applications were previously considered by GTTAC at the 22 July 2004 meeting and by individual GTTAC members in December 2004. Details of that meeting are documented in GTTAC Communiqué 13 which is available from the OGTR website.

At the 23rd GTTAC Meeting (March 2005) members were briefed on the decisions on these licence applications.

- **DIR 051/2004 – Field trial of sugarcane expressing sucrose isomerase (University of Queensland)**

This proposed dealing involves the intentional release of genetically modified (GM) sugarcane into the environment on a limited scale and under controlled conditions at 2 sites covering maximum total area of 3.55 ha in the Burdekin Shire, Queensland. The applicant has proposed that the release will occur between early 2005 and late 2010. Plantings are proposed to take place during March-May and August-October in each of 2005, 2006 and 2007.

The proposed trials involve up to 120 transgenic lines of GM sugarcane containing the sucrose isomerase (*si*) gene isolated from the bacterium *Panthoea dispersa* and the aminoglycoside resistance gene (*aphA* or *nptII*) from the bacterium *Escherichia coli* as a selectable marker. The *si* gene transferred into the GM sugarcane confers upon the plant the ability to express the sucrose isomerase enzyme which converts sucrose into its isomer isomaltulose.

The aims of the proposed release are to:

- determine the agronomic performance of the GM sugarcane lines under field conditions including concentrations of different sugars in various tissues over the growing season; and

- observe the presence of any indirect effects caused by the genetic modifications eg. alteration of sensitivity to environmental and biological stress.

GTTAC considered the RARMP for DIR 051/2004 and advised the Regulator that:

- the risk assessment identifies all risks associated with the release and recommends that the risk of weediness, allergenicity and toxicity may be better classified as 'negligible'; and

- the Committee agrees with the proposed licence conditions and recommends that the monitoring period for this perennial species should be greater than 12 months.

- **DIR 052/2004 - Phenotyping of T-DNA and/or transposon Ds insertion line of rice (Oryza sativa L) under field conditions (CSIRO).**

The proposed dealing involves the intentional release of genetically modified (GM) rice (*Oryza sativa* L. cv Nipponbare) into the environment, on a limited scale and under controlled conditions.

CSIRO proposes to carry out the release at one site in the local government area of Wagga Wagga City Council, NSW over three growing seasons between October 2004 and May 2008, including provision for one fallow season if required. However, the statutory timeframe for consideration of the application extends until February 2005. Therefore if a licence were to be issued it would be likely to cover the growing seasons between 2005 and 2009.

The aims of the proposed release are:

- to identify rice genes influencing traits of biological or agronomic interest by observing alterations in the visible characteristics (phenotypes) of GM rice lines which were generated under contained (laboratory and glasshouse) conditions; and

- to characterise gene flow in rice under Australian field conditions.

The proposed trial involves the planting of approximately 1500 different GM rice lines (usually 30 plants of each line). The lines contain various combinations of commonly used reporter genes and antibiotic resistance and herbicide tolerance genes as selectable markers, as well as transposable *Ds* elements and 'plasmid rescue' elements.

GTTAC considered the RARMP for DIR 052/2004 and advised the Regulator that:

- the risk assessment identifies all risks associated with the release;

- the risk of weediness should be negligible rather than low;

- no additional data needs to be collected apart from gene flow data. Replication of previous work on the field biology of rice should not be required; and

- the Committee agrees with the proposed licence conditions and recommends that:

    - site 2 should be surrounded by 40 cm high earth banks; and

    - the edges of the cage covering the sites should be required to be in contact with the ground around its entire perimeter;

## Presentations

The following presentations were made to GTTAC:

- Introduction to the assessment process for Dealings Involving the Intentional Release of GMOs into the environment (DIRs) (OGTR);

- Introduction to the assessment for Dealings Not involving Intentional Release of GMOs into the environment (DNIRs) (OGTR);

- Risk Analysis Framework (OGTR);
- Horizontal Gene Transfer (OGTR); and
- Public Perceptions of Science and Biotechnology (Biotechnology Australia).

## Review of the *Gene Technology Regulations 2001* (the Regulations)

GTTAC members met by teleconference on 31 May 2005 and discussed the following documents regarding the review of the Regulations:

- Consideration of exempt dealings with respect to transgenic mice and rats and the review of the *Gene Technology Regulations 2001*
- Consideration of the review of the *Gene Technology Regulations 2001*

The draft revised Regulations will be made available for public comment later in the year.

## 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/