GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE

This is the third communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the fourth and fifth meetings of GTTAC held on 26 March 2002 (teleconference) and 24 April 2002 respectively.

GTTAC is a statutory advisory committee to the Gene Technology 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 all applications for licences to conduct dealings with GMOs and comment on the Risk Assessment and Risk Management Plan (RARMP) that is prepared in respect of each application.

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 on those applications and RARMPs.

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

RARMPs for licence applications for Dealings involving the Intentional Release of genetically modified organisms (DIRs) are 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 the document.

1. Dealings Not Involving the Intentional Release of Genetically Modified Organisms

1.1 Input to the preparation of, and advice on, RARMPS for DNIRs (in numerical order of receipt)

Rapid Methods for the Detection of Toxic Cyanobacteria (DNIR 010)

The Australian Water Quality Centre has applied for a licence to identify the genes associated with toxin synthesis in cyanobacteria and to construct cyanobacteria that do not produce the toxin.

GTTAC noted that there were several minor issues requiring further information with respect to this application. While they did not affect the level of risk involved, the applicant should be requested to provide the information.

GTTAC resolved to advise the Regulator:

. The risk assessment identifies all the risks associated with the proposed dealings.

. The measures proposed in the risk management plan are adequate to deal with the identified risks.

. The following matters should be considered in finalising the RARMP:

- Clarification of the statement concerning the destruction of cyanobacteria and toxins by chlorination, microfiltration or oxonation.
- Clarification of the statement in the RARMP about possible production of the toxin in *E. coli*.
- Explanation of the statements concerning the ability of *E. coli* to survive in the environment and to cause disease.
- Provision of references to support the statement that '… the precursors and cofactors required for synthesis of the toxin are unlikely to be present *in E. coli.*'

Cryptoccal phospholipases: Structure and Potential Targets for Therapeutics (DNIR 011)

Western Sydney Area Health Service has applied for a licence to study the structure and function of the phospholipase proteins in the fungus *Cryptococcus neoformans*.

GTTAC resolved to advise the Regulator:

. The risk assessment identifies all the risks associated with the proposed dealings.

. The measures proposed in the risk management plan are adequate to deal with the identified risks.

Investigation of the Roles of TNFα-related apoptosis-inducing ligand (TRAIL) in the Immune System (DNIR 012)

Western Sydney Area Health Service has applied for a licence to investigate the function of TRAIL in the immune system. TRAIL is a molecule which is thought to specifically kill transformed and virus infected cells but not most normal human cells.

GTTAC resolved to advise the Regulator:

. The risk assessment identifies all the risks associated with the proposed dealings.

. The measures proposed in the risk management plan are adequate to deal with the identified risks.

Studies of Cell Growth and Survival (DNIR 013)

Western Sydney Area Health Service has applied for a licence to investigate the biological processes that regulate cell growth and survival.

GTTAC resolved to advise the Regulator:

. The risk assessment identifies all the risks associated with the proposed dealings.

. The measures proposed in the risk management plan are adequate to deal with the identified risks.

Reverse Genetics of Newcastle Disease Virus (DNIR 017)

The Commonwealth Scientific and Research Organisation (CSIRO), Australian Animal Health Laboratory, has applied for a licence to determine the role of the matrix protein gene in Newcastle Disease Virus.

GTTAC noted that there were several minor issues requiring further information with respect to this application. While they did not affect the level of risk involved, the applicant should be requested to provide the information.

GTTAC resolved to advise the Regulator:

. The risk assessment identifies all the risks associated with the proposed dealings.

. The measures proposed in the risk management plan are adequate to deal with the identified risks.

. In finalising the RARMP, additional information should be sought on the following matters:

- The methods used to transfer genes.
- Scientific literature on whether the modification made to the matrix gene could impact on virus virulence.
- The details of the animal facility in which the work would be carried out; and the proposed disposal methods for infected animals.

Bone Repair (DNIR 018)

CSIRO, Division of Molecular Sciences, has applied for a licence to identify genes that regulate bone growth and their most effective routes for administration in order to enhance bone repair.

GTTAC resolved to advise the Regulator:

. The risk assessment identifies all the risks associated with the proposed dealings.

. The measures proposed in the risk management plan are adequate to deal with the identified risks.

B55 Gene Over-expression in *Psammomys obesus* (DNIR 019)

Deakin University has applied for a licence to study the effects on obesity and diabetes of over-expression of the B55 gene.

GTTAC resolved to advise the Regulator:

. The risk assessment identifies all the risks associated with the proposed dealings.

. The measures proposed in the risk management plan are adequate to deal with the identified risks.

HIV Replication and Gene Expression (DNIR 021)

The Royal Children's Hospital, Brisbane has applied for a licence to investigate the role of virus regulatory proteins in HIV replication and gene expression.

GTTAC noted that there were several issues related to the handling of HIV that required further clarification by the applicant.

GTTAC resolved to advise the Regulator:

. The risk assessment identifies all the risks associated with the proposed dealings.

. The measures proposed in the risk management plan are adequate to deal with the identified risks.

. In finalising the RARMP, additional information should be sought from the applicant on the measures proposed to avoid the production of a virus with increased virulence and those aspects of the work which will be carried out in PC3 conditions.

Characterisation of the Anti-apoptotic Function of P-glycoprotein and Transcriptional Regulation of the MDR1 Gene (DNIR 022)

The Peter MacCallum Cancer Institute has applied for a licence to determine if the P-glycoprotein can protect tumour and normal cells against cell death.

GTTAC resolved to advise the Regulator:

. The risk assessment identifies all the risks associated with the proposed dealings.

. The measures proposed in the risk management plan are adequate to deal with the identified risks.

Production of Recombinant Proteins in Mammalian, Insect, Yeast and Bacterial Cells (DNIR 024)

Biotech Australia Pty Ltd has applied for a licence to produce a large range of recombinant proteins for research reagents, clinical research and commercial biopharmaceuticals.

GTTAC noted that the purpose of the application was to streamline the application process for dealings that would otherwise be exempt from licensing if it were not for the fact they involved production volumes of greater than 10 litres of culture. The licence issued for these dealings would require that the OGTR is notified of the protein to be produced and the host/vector system to be employed before production commences.

GTTAC resolved to advise the Regulator:

. The risk assessment identifies all the risks associated with the proposed dealings.

. The measures proposed in the risk management plan are adequate to deal with the identified risks.

2. Dealings Involving the Intentional Release of Genetically Modified Organisms

2.1 Advice on Applications (in numerical order of receipt)

Commercial Release of Bollgard II® Cotton (DIR 012)

Monsanto Australia Ltd has applied for a licence for the commercial release of a genetically modified insecticidal type of cotton registered under the trade name Bollgard II® cotton and a type of genetically modified insecticidal cotton that is also herbicide tolerant, referred to as Bollgard II®/Roundup Ready® cotton.

The GM cotton plants and their by-products would be used in the same manner as conventional cotton, including for human food. The Australian New Zealand Food Authority (ANZFA) has approved the use of INGARD®, Bollgard II® and Roundup Ready® cotton and relevant by-products in human food. In two previous assessments of Bollgard II® cotton, ANZFA indicated that it considers products from Bollgard II® cotton to be as safe for human consumption as those from conventional cotton. There is no protein or DNA in cotton seed oil or linters after processing for either GM or non-GM cotton.

The proposed releases would be carried out in all cotton growing areas including potential areas north of latitude 22° South in Queensland, the Northern Territory and Western Australia. It is proposed that ultimately, the total release would comprise a high proportion of Australia's cotton growing hectarage (currently about 484, 000 ha), although the exact area would be subject to an insect resistance management strategy.

GTTAC resolved to advise the Regulator:

. The following potential hazards should be addressed in the RARMP for application DIR 012.

(a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
(b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

. In addition, the following data should be obtained:

- a copy of the report on the potential weediness of GM cotton in northern Australia
- information on the extent to which cotton growers have complied with insect resistance management strategies (IRM) for INGARD® cotton
- data, at a regional scale and from an existing tropical cotton growing area such as Emerald, QLD, on the efficacy of the IRM strategy developed for INGARD® cotton
- more detailed data on the potential linkage of the Cry1Ac, Cry2Ab and CP4 EPSPS transgenes and associated segregation ratios.

Agronomic Assessment and Seed Increase of INGARD® and Bollgard II® Cotton (DIR 013)

Monsanto Australia Ltd has applied for a licence for the limited and controlled release of a genetically modified insecticidal type of cotton registered under the trade name Bollgard II® cotton, INGARD® cotton and a type of genetically modified insecticidal cotton that is also herbicide tolerant, referred to as Bollgard II®/Roundup Ready® cotton.

The purpose of the proposed release is to continue the agronomic and varietal assessment of promising cotton lines; increase seed of the most promising Bollgard II® and Bollgard II/Roundup Ready® cotton lines for future releases (which would be subject to additional applications); further the development of the Insect Resistance Management Plan for Bollgard II®.

The GM cotton plants and their by-products would be used in the same manner as conventional cotton, including for human food. The Australian New Zealand Food Authority (ANZFA) has approved the use of INGARD®, Bollgard II® and Roundup Ready® cotton and relevant by-products in human food. In two previous assessments of Bollgard II® cotton, ANZFA indicated that it considers products from Bollgard II® cotton to be as safe for human consumption as those from conventional cotton. There is no protein or DNA in cotton seed oil or linters after processing for either GM or non-GM cotton.

The releases would be carried out in all cotton growing areas of New South Wales and Queensland including potential cotton growing areas near Richmond, QLD, north of latitude 22° South.. The release would be over a total area of 10 000 hectares. No limitations on transportation, cultivation or storage are proposed, other than compliance with an insect resistance management strategy, which is yet to be finalised.

GTTAC resolved to advise the Regulator:

. The following potential hazards should be addressed in RARMP for application DIR 013.

(a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
(b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

Agronomic Assessment and Seed Increase of Transgenic Cotton Expressing the *Cry1Ac* and *Cry2Ab* Genes from *Bacillus thuringiensis* (DIR 014)

The Commonwealth Scientific and Industrial Research Organisation (CSIRO) has applied for a licence for the limited and controlled release of a genetically modified insecticidal type of cotton registered under the trade name INGARD®, Bollgard II® and a type of genetically modified insecticidal cotton that is also herbicide tolerant, referred to as Bollgard II®/Roundup Ready® cotton.

The purpose of the proposed release is for agronomic assessment, to produce seed for future releases and to assess the efficacy of insect control in unsprayed plots. The release would be carried out on 20 sites and involve a total area of 42 hectares in NSW and Queensland.

GTTAC resolved to advise the Regulator:

. The following potential hazards should be addressed in the RARMP for application DIR 014.

(a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
(b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

Agronomic Assessment and Seed Increase of Transgenic Cotton Expressing Tolerance to the Herbicide Glufosinate Ammonium (DIR 015)

CSIRO has applied for a licence for the limited and controlled release of a genetically modified insecticidal type of cotton expressing tolerance to glufosinate-ammonium, the active constituent of herbicides Basta® and Liberty® (hence the name Liberty® cotton), which would be carried out in New South Wales.

The purpose of the proposed release is to trial Liberty® cotton for agronomic assessment, and to produce seed for future releases (which would be subject to further approvals). The release would be carried out on one site over a total area of two hectares in New South Wales.

GTTAC resolved to advise the Regulator:

. The following potential hazards should be addressed in the RARMP for application DIR015.

(a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
(b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

Evaluation under Field Conditions of Sub-clover Stunt Virus Promoters Driving an Insect Tolerance Gene (*Cry1Ac*) from *Bacillus thuringiensis* (DIR 016)

CSIRO has applied for a licence for the limited and controlled release of a genetically modified cotton containing the *cry1Ab* and *bar* genes which confer insecticidal activity and herbicide tolerance, respectively. The proposed trial would mainly involve the evaluation of a novel set of promoters from the sub-clover stunt virus which were used to drive the *cry1Ab* gene and to produce seed for future releases (which would be subject to further approvals).

The trial would be carried out on 2 sites over a total area of 1.5 hectares in New South Wales.

GTTAC resolved to advise the Regulator:

. The following potential hazards should be addressed in the RARMP for application DIR 016.

(a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
(b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

Agronomic Assessments and Efficacy Studies of Transgenic Cotton Expressing a New Insecticidal Tolerance Gene (DIR 017)

CSIRO has applied for a licence for the limited and controlled release of a genetically modified cotton expressing a new insecticidal gene which is subject to an application for protection as commercial confidential information.

The purpose of the proposed release is to trial the new insecticidal cotton for agronomic assessment and efficacy studies, and to produce seed for future releases (which would be subject to further approvals). The release would be carried out on 3 sites over a total area of 3 hectares in New South Wales.

GTTAC resolved to advise the Regulator:

. The following potential hazards should be addressed in the RARMP for application DIR 016.

(a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
(b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

. In addition, the following information should be requested from the applicant:

- data on the toxicity of the new insecticidal genes to non-target insects and their expression levels and efficacy on target insects.

3. Other Matters

Antibiotic Resistance Marker Genes

GTTAC was advised that the Office of the Gene Technology Regulator proposed to undertake a review of the use of antibiotic resistance marker genes (ARMGs) in Australia. The Committee noted that there was public concern about the development of antibiotic resistance. ARMGs in genetically modified organisms were thought, by some, to contribute to the development of antibiotic resistance and reduce the usefulness of antibiotics in treating infections.

GTTAC advised the Regulator that there was no evidence to support this view and that the risk to human health and safety or the environment from the use of antibiotic resistance marker genes is negligible.

Genetically Modified Canola

At the request of the Regulator GTTAC has begun to give more detailed consideration to the issues surrounding the possible commercial release of GM Canola in Australia as an application seeking the general release of GM Canola had been foreshadowed. To this end the Committee held a teleconference held on 10 April 2001 dedicated to the identification and initial consideration of the possible impacts the release of GM Canola may have on the health and well being of people and the environment and of any the data that would be required for the Committee to fully assess an application seeking the general release of GM Canola.

Enquiries and Risk Assessment and Risk Management Plans

For all enquiries and to obtain copies of Risk Assessment and Risk Management Plans for dealings involving the intentional release of GMOs into the environment please phone the OGTR on 1800 181 030. The Plans are also available electronically from our website at http://www.ogtr.gov.au/publications/riskassessments.htm

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