GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE

This is the fifth communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the eighth meeting of GTTAC held on 22 August 2002.

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 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 (DNIRs)

DNIRs are dealings 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.

GTTAC has advised that all researchers involved with DNIRs need to follow the appropriate laboratory guidelines relating to their facility certification. In particular, GTTAC has advised that the use of sharp instruments should be avoided where the possibility of accidental inoculation exists. However, when sharps are required, extra care should be taken.

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

Molecular interactions between HIV-1 and host gene products (DNIR 038)
Impact of host gene products on HIV-1 replication in mammalian cells (DNIR 039)
Effect of host gene products that interact with HIV-1 reverse transcriptase on MoMLV replication (DNIR 040)

GTTAC considered three applications from the Macfarlane Burnet Institute for Medical Research and Public Health for licences to test the impact of the expression of cellular proteins on HIV-1 and MLV replication in mammalian cell culture.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that the measures proposed in the risk management plan are adequate to deal with the identified risks. GTTAC recommended that the development of separate RARMPs for these applications would assist in more clearly delineating the risks involved with each individual dealing and the precautions that should be followed by operators.

Characterisation of the signalling and cell biology of CD46 and the Dlg family (DNIR 041)

The aim of the proposed dealing is to study the effects on immune cell function of the protein CD46 and the Dlg family in human and mouse cells.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

A preclinical model of pancreatic islet xenotransplantation as treatment for Type 1 diabetes (DNIR049)

This dealing aims to produce pig and mouse pancreatic islet cells that do not provoke a response in the human immune system.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

Molecular pathogenesis of *Bartonella henselae* (DNIR 052)

The aim of the proposed dealing is to study *Bartonella henselae,* a bacterium which causes cat-scratch disease. GTTAC suggested the immunocompromised people should be advised against working on the project and that a contingency plan should be developed in the event of accidental injection.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

Transfection of *Plasmodium falciparum* (DNIR 057)

The aim of the proposed dealing is to study the parasite which causes malaria, *Plasmodium falciparum*.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

Expression of genes in *Leishmania* (DNIR 058)

The aim of the proposed dealing is to study the parasite *Leishmania* and immune responses to the parasite in mice.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that 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 Cotton

Commercial release of Bollgard II® Cotton (DIR 012)

Monsanto Australia Ltd has applied for a licence for the commercial release of an insecticidal cotton (Bollgard II®) and an insecticidal/herbicide tolerant combination cotton (Bollgard II®/Roundup Ready®). Bollgard II®/Roundup Ready® was produced by the conventional crossing of genetically modified Bollgard II® with genetically modified Roundup Ready® that contains the gene for tolerance to the herbicide glyphosate (Roundup®).

The application sought to cover all Australian cotton growing areas, including areas north of latitude 22° South, in the Northern Territory, Western Australia and Queensland. The OGTR, however, advised that due to concerns expressed about the potential weediness of GM cotton in northern Australia, it was proposed that the release be restricted to cotton growing areas below 20° South and only limited and controlled releases would be permitted in areas above 20° South.*

GTTAC:

(a) endorsed the Risk Assessment and Risk Management Plan for DIR 012;

(b) agreed with the proposal to restrict the growing of GM cotton to areas below 20° South and that a roadside sampling program to monitor for the presence of volunteer GM cotton should be required; and

(c) endorsed the proposed licence conditions for DIR 012 with the recommendation that the following additional matters be considered in finalising the RARMP:

- monitoring dairies and their immediate surrounds for the presence and destruction of volunteers;
- double bagging, or covering of GM cotton seed and seed material by tarpaulins while being transported in areas above latitude 20° South;
- approaching the Cotton Research and Development Corporation to discuss the conduct of research into gene flow and environmental impacts of GM cotton; and
- permitting crop size to be determined by market forces and any conditions set by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA).

** NB. Based on additional information received during the consultation on the RARMP, the release was restricted to south of latitude 22º South, because of concerns about the potential weediness of the cotton in tropical areas, as well as the potential for out-crossing to native cotton species in areas north of that latitude.*

2.2 Advice on Sugarcane

Agronomic Assessment of Transgenic Sugarcane engineered with Reporter Genes (DIR 019)

The Bureau of Sugar Experiment Stations (BSES) has applied for a licence for the limited and controlled release of genetically modified sugarcane. The sugarcane has been produced through a new rapid tissue culture process combined with genetic modification.

The GM sugarcane contains three new genes. The first gene, *nptII* is derived from the bacterial Tn5 transposon and encodes resistance to the antibiotics kanamycin, neomycin and geneticin. This antibiotic resistance trait was used as a selectable marker in the initial laboratory stages to select sugarcane plants that were genetically modified. A second gene, *bla* from the bacterium *Escherichia coli,* encodes ampicillin resistance. It is linked to a bacterial promoter that does not function in plants, so the protein is not produced in sugarcane. The third gene, *gfp,* is derived from the jellyfish *Aequorea victoria* and encodes a reporter protein, green fluorescent protein. The protein is readily detected due to its fluorescent properties and provides an indication of whether, and to what extent, the gene is expressed.

Short regulatory sequences that control the expression of the *nptII* and *gfp* genes are also present in the GM sugarcane. These are derived from maize and a common soil bacterium, *Agrobacterium*. Although *Agrobacterium* is a plant pathogen, the regulatory sequence comprises only a small part of its total genome and is not capable of causing disease.

The aim of the proposed release is to test the effect of both the new tissue culture process and genetic modification on the agronomic performance of the GM sugarcane. The release would be carried out over four growing seasons on one site over a total area of 0.7 ha in the Cairns district in North Queensland.

GTTAC advises the Regulator:

(a) The following risks or potential risks should be assessed in relation to the GM sugarcane application from the BSES:

- toxicity or allergenicity of the genetically modified sugarcane;
- weediness or increased potential for weediness;
- potential for the introduced genes to cross into other organisms.

(b) The risk management plan should include measures to prevent the spread or persistence of the GMO or its genetic material in the environment.

(c) In addition, GTTAC recommends that monitoring for volunteers be carried out for a period of six months.

2.3 Advice on Canola

GTTAC considered two applications for the proposed release of GM canola in Australia.

General Release of Roundup Ready® Canola (*Brassica napus*) in Australia (DIR 020)

The OGTR has received an application from Monsanto Australia Ltd (Monsanto) for a licence for the intentional release of GM Canola that has been modified to tolerate glyphosate, the active ingredient in the herbicide Roundup®.

Monsanto proposes the commercial cultivation of Roundup Ready® canola in all the current and future canola growing regions of Australia, which potentially includes New South Wales, Victoria, South Australia, Western Australia, Queensland, Tasmania and the Australian Capital Territory. The Tasmanian State Government currently has a moratorium on the planting of GM plants in that State through the *Plant Quarantine Act 1997* (TAS). Accordingly, in addition to a licence issued under the Gene Technology Act 2000 (CWLTH) and corresponding State laws, any release of Roundup Ready® canola in Tasmania would also require approval from the Tasmanian State Government. The use of genetically modified crops in Tasmania is currently restricted to approved research trials and no approval would be considered for any commercial planting.

Monsanto proposes a phased introduction of Roundup Ready® canola which enables the use of glyphosate for weed control with a limited release of approximately 5000 hectares in the first year (2003) in the canola growing regions of south eastern Australia. Monsanto expects a steady increase in the area sown to Roundup Ready® canola over a number of years across the canola growing regions of Australia, with the rate of increase being determined by market acceptance and seed and variety availability. Monsanto proposes to continue to work closely with the grains industry to manage the introduction of Roundup Ready® canola. Glyphosate is not currently registered for use on canola by the NRA.

The canola plants and their by-products, would be used in the same manner as conventional canola, including for human food and animal feed. After harvest of the Roundup Ready®

canola, the grain will enter the general commerce supply chain in Australia for domestic and export markets. Canola is grown commercially primarily for its seeds which yield about 40% oil and a high protein animal feed. Canola oil, which does not contain genetic material, is used in the manufacture of a variety of food products. Canola meal is primarily used as a feed for livestock, but it is also used in poultry and fish feed, pet foods and fertilisers.

Monsanto proposes a systematic and strategic approach to risk management and product stewardship through the implementation of its Roundup Ready Canola Technology Stewardship Strategy, which includes a Roundup Ready Canola Crop Management Plan. These will be consistent with the Guidelines for Industry Stewardship Programs and Crop Management Plans proposed by the Plant Industries Committee of the Primary Industries Standing Committee (under the Primary Industries Ministerial Council) and the Guidelines for Supply Chain Management of GM Canola being developed by the Gene Technology Grains Committee.

GTTAC advises the Regulator that:

(a) The following risks or potential risks, especially given the commercial scale of the release, should be assessed in relation to the Roundup Ready canola application from Monsanto:

- toxicity or allergenicity of Roundup Ready canola;
- weediness or increased potential for weediness, including the persistence of canola in non-agricultural habitats and the factors determining such persistence;
- potential for the introduced genes to be transferred to into other organisms by cross pollination; and
- any other potential hazards, including whether commercial release is likely to result in changes to agricultural practices that may have an environmental impact.

(b) The potential for glyphosate tolerant canola to occur along roadsides does not present a significant risk to the environment.

(c) In addition, the applicant should be requested to provide further information on glucosinolate production and to provide a crop management plan.

(d) The inclusion of data on the chromosomal location of the transgenes in the molecular characterisation of the GMO would be useful if available. However, is not absolutely required for the assessment.

(e) The applicant should be required to provide a detailed herbicide resistance management plan and any recommendations made regarding supply chain management.

Commercial Release of InVigor® Hybrid Canola (*Brassica napus*) for use in the Australian Cropping System (DIR 021)

The OGTR has received an application from Aventis CropScience Pty Ltd (Aventis) for a licence for the intentional release of a GMO into the environment. The aim of the proposed release is to allow the commercial use of InVigor® canola lines T45, Topas 19/2, MS1, MS8,

RF1, RF2 and RF3 in Australian agriculture and continuing product research and development programs based on these lines.

Aventis only proposes to commercialise InVigor® hybrid canola derived from MS8 and RF3 lines for use by Australian farmers. Canola derived from T45, Topas 19/2, MS1, RF1 and RF2 lines has been approved for food and environmental release in a number of other countries and Aventis is also seeking approval for these lines to achieve consistency with existing overseas regulatory approvals.

InVigor® canola plants have been genetically modified to introduce a hybrid breeding system based on male sterile (MS) and fertility restorer (RF) lines, and to be tolerant to the herbicide glufosinate ammonium, the active ingredient in the herbicides Liberty® and Basta®. Lines T45 and Topas 19/2 have been genetically modified to introduce glufosinate ammonium tolerance, but do not contain the hybrid breeding system. Aventis have indicated that the use of InVigor® canola will also provide the option of using herbicides which have glufosinate ammonium as their active ingredient, in conjunction with other measures, for the control of weeds in the crop. Liberty® is not currently registered by the NRA for use on canola. Basta® is registered by the NRA for use in horticulture.

The canola lines Topas 19/2, MS1, RF1 and RF2 also contain the *nptII* gene from the bacterium *Escherichia coli* which confers resistance to some aminoglycosides including the antibiotics neomycin, kanamycin and gentamicin. The antibiotic resistance trait was used as a selectable marker in the initial laboratory stages to select canola plants that were genetically modified.

Aventis proposes the commercial cultivation of InVigor® canola potentially over all the current and future canola growing regions of Australia, which includes New South Wales, Victoria, South Australia, Western Australia, Queensland, Tasmania and the Australian Capital Territory. However, as noted for DIR 020, release in Tasmania would also require the approval of the Tasmanian Government which has imposed a moratorium on the cultivation of GM food crops under its Plant Quarantine Act.

Aventis proposes a phased introduction of InVigor® canola with a limited release in the first year (2003), including seed increase and demonstration sites. Aventis expects that the scale of the release will expand slowly and that the scale of the expansion will be dependent on market acceptance, seed and variety availability. Aventis proposes to work closely with the canola industry to manage the introduction of InVigor® canola.

Aventis proposes to implement a stewardship program for the management of InVigor® canola. The stewardship program, including the Crop Management Plan for InVigor® canola, will be consistent with the Guidelines for Supply Chain Management of GM Canola being developed by the Gene Technology Grains Committee.

GTTAC advises the Regulator:

(a) The following risks or potential risks, especially given the commercial scale of the release, should be assessed in relation to the InVigor® canola application from Aventis:

- toxicity or allergenicity of InVigor canola;

- weediness or increased potential for weediness, including the persistence of canola in non-agricultural habitats and the factors determining such persistence;
- potential for the introduced genes to be transferred to into other organisms by cross pollination;
- any other potential hazards, including whether commercial release is likely to result in changes to agricultural practices that may have an environmental impact; and
- any hazards associated with the *nptII* gene.

(b) The RARMP should include a provision that glufosinate-ammonium tolerant canola should not be grown in vineyards. Glufosinate-ammonium is used to control weeds in vineyards.

(c) Inclusion of data on the chromosomal location of the transgenes in the molecular characterisation of the GMO, would be useful if available. However, this is not absolutely required for the assessment.

(d) In addition, the applicant should be requested to provide a detailed crop management plan, including a resistance management plan and any provisions made regarding supply chain management.

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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