
GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE No. 6

This is the sixth communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the ninth and tenth meetings of GTTAC held on 19 September and 24 October 2002 respectively.

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 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.

RARMPs for the following DNIRs were assessed:

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 063 Retroviral mediated gene transfer into murine haematopoietic cells</p>	<p>The researchers propose to transfer and study genes thought to be involved in cell growth, proliferation, apoptosis (programmed cell death) and differentiation in cell cultures.</p>	<p>GTTAC agreed that the risk assessment identified all the risks associated with the proposed dealings and that the measures proposed in the risk management plan are adequate to deal with the identified risks. GTTAC advised that laboratory guidelines must be followed and in particular, 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.</p>
<p>DNIR 065 Immunotherapy of cancer using recombinant viruses</p>	<p>This project aims to assess the anti-tumour potential of a melanocyte protein vaccine.</p>	<p>As for DNIR 063. GTTAC also recommended that the development of autoimmune responses be considered. In addition researchers should be vaccinated against <i>vaccinia</i>.</p>
<p>DNIR 067 Development of vaccines to protect against members of the <i>Pasteurellaceae</i></p>	<p>This project aims to develop vaccines against <i>Pasteurellaceae</i> associated diseases in production animal species.</p>	<p>As for DNIR 063.</p>
<p>DNIR 068 Fowl adenovirus recombinants</p>	<p>The proponents intend to construct and test different genetically modified fowl adenoviruses as potential vaccines against diseases in chickens and dogs.</p>	<p>As for DNIR 063.</p>
<p>DNIR 071 JE Chimerivax</p>	<p>The aim is to test the safety and efficacy of a yellow fever vaccine genetically modified to vaccinate against Japanese encephalitis in human volunteers.</p>	<p>As for DNIR 063.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 072 Construction of recombinant ranaviruses</p>	<p>Ranaviruses are viruses of fish, frogs and reptiles and this project aims to develop technology to genetically modify these viruses.</p>	<p>As for DNIR 063.</p>
<p>DNIR 076 Generation of infectious <i>cucumber mosaic virus</i> clones</p>	<p>Cucumber mosaic virus is a disease of lupins and many other plants. The researchers intend to study the interactions between the virus and lupins.</p>	<p>As for DNIR 063.</p>
<p>DNIR 077 Bioassay evaluation of bacteria expressing insecticidal genes</p>	<p>The aim of DNIR 077 is to identify proteins toxic to the rice bloodworm <i>Chironomus tepperi</i> from bacteria.</p>	<p>As for DNIR 063.</p>
<p>DNIR 078 Toxicity of modified rice callus to <i>Chironomus</i> larvae</p>	<p>The aim of DNIR 078 is to insert and test proteins toxic to the rice bloodworm <i>Chironomus tepperi</i> in tissue cultures of rice.</p>	<p>As for DNIR 063.</p>
<p>DNIR 079 Development of new vaccines against tuberculosis</p>	<p>The aim is to develop and test vaccines to protect against the human bacterial disease tuberculosis.</p>	<p>As for DNIR 063.</p>
<p>DNIR 080 Packaging of hepatitis delta virus (HDV) with modified envelope protein</p>	<p>The researchers propose to genetically modify hepatitis delta virus (HDV) so that it can infect cells other than liver cells, such as cancer cells, as a potential treatment.</p>	<p>As for DNIR 063.</p>
<p>DNIR 081 Molecular analysis of <i>Streptococcus pyogenes</i></p>	<p>The aim is to understand the role of specific gene products of the bacteria <i>Streptococcus pyogenes</i> in the onset of disease and to develop vaccines to protect against the disease.</p>	<p>As for DNIR 063. In addition, GTTAC advised that the vaccination of operators is not recommended.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 082 Molecular analysis of <i>Mycoplasma hyopneumoniae</i> and vaccine development</p>	<p>The aim is to understand the role of specific gene products of the bacterium <i>Mycoplasma hyopneumoniae</i> in the onset of disease and to develop vaccines to protect against the disease.</p>	<p>As for DNIR 063.</p>
<p>DNIR 084 The role of SDF-1 in normal and leukemic pre-B cell interactions with bone marrow stroma</p>	<p>SDF-1 is thought to be a key regulator of the behaviour of cells involved in acute lymphoblastic leukemia and this project aims to study how it works.</p>	<p>As for DNIR 063.</p>
<p>DNIR 085 Analysis of the effects of CD44 variant exon expression on adhesion and migration of human leukemia cells</p>	<p>CD44 is thought to affect cells involved in myeloid leukemia and this project aims to study how variations of CD44 act.</p>	<p>As for DNIR 063.</p>
<p>DNIR 091 Recombinant vaccinia virus encoding CMV or HCV genes</p>	<p>The aim is to examine the host response to cytomegalovirus and hepatitis C virus proteins to test for protective immune responses.</p>	<p>As for DNIR 063. In addition GTTAC advised that there was no evidence to suggest that viruses from different families could complement each other to produce replication competent chimeric viruses.</p>
<p>DNIR 092 Molecular mechanisms of bone and tissue remodelling</p>	<p>The aim is to introduce genes of interest into primary human and rodent cell lines of bone origin to study the effects of their forced expression on the formation of bone and other connective tissue.</p>	<p>As for DNIR 063.</p>
<p>DNIR 093 Novel retroviral expression cloning strategies to isolate genes with roles in haemopoiesis and stromal biology</p>	<p>The aim is to isolate novel cDNAs that encode for proteins that regulate haemopoietic and stromal cell differentiation. This will be achieved using retroviral expression cloning techniques.</p>	<p>As for DNIR 063.</p>

Application Number and Title	Project Description	GTTAC Comments
DNIR 094 Clinical protocol HVDDT NO1 AI-05395 – fowlpox virus	The aim of these dealings is to determine the safety and immunogenicity of an HIV vaccine regimen.	As for DNIR 063.
DNIR 095 Clinical protocol HVDDT NO1 AI-05395 – DNA vaccine	The aim of these dealings is to determine the safety and immunogenicity of an HIV vaccine regimen.	As for DNIR 063.

DNIR licence for the importation of stock feed

- **Importation of soy beans for use as stockfeed**

Due to the current drought, an application is anticipated requesting approval to import soy beans as stockfeed from the U.S.A, a proportion of which may be genetically modified. GTTAC advised that the RARMP prepared with respect to this application should address all risks associated with the importation of GM soy beans. GTTAC suggested that the risk management plan should also identify measures to recover any seed spilled at the processing plant. In addition, GTTAC questioned the licence condition requiring the processing plant to be within 20km of the wharf. This condition is required by AQIS and all plants are AQIS approved.

Dealings Involving the Intentional Release of Genetically Modified Organisms

Dealings Involving the Intentional Release (DIRs) of GMOs are dealings that are undertaken outside of a contained facility. DIRs may range from the limited and controlled release (field trial) of a GMO to a commercial (general) release of a GMO.

RARMPs for licence applications for 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 this document.

Advice on Cotton

GTTAC considered the RARMPs prepared in response to four applications concerning the release of transgenic cotton in Australia, and provided advice on issues to be considered in preparing RARMPs for four others.

Advice on Cotton RARMPs

- **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 (field trial) of two types of genetically modified (GM) cotton, Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton, into the environment.

Bollgard II[®] cotton is resistant to the major caterpillar pests that attack cotton. It contains two insecticidal genes that produce proteins toxic to specific insects and was derived from INGARD[®] cotton which contains one of the insecticidal genes. Bollgard II[®]/Roundup Ready[®] cotton was produced by conventional breeding of Bollgard II[®] cotton with Roundup Ready[®] cotton that contains a gene for tolerance to glyphosate, the active ingredient in the herbicide Roundup[®]. Bollgard II[®]/Roundup Ready[®] cotton therefore contains the two insecticidal genes from Bollgard II[®] cotton as well as the glyphosate tolerance gene from Roundup Ready[®] cotton.

CSIRO proposes to carry out a release on a total of 20 sites in NSW and Qld, covering a total area of 42 hectares. The purpose of this release is to continue evaluation of the agronomic performance of a number of different GM cotton lines, and to produce seed for possible future releases (which would be subject to separate application and assessment processes). In addition, the efficacy of the insecticidal proteins in controlling insect pests will be evaluated.

GTTAC advised the Regulator that the RARMP prepared for DIR 014 covered all relevant issues. The Committee agreed with the main conclusions from the risk assessment, including that:

- the Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton is not likely to prove more toxic or allergenic to humans or other organisms (other than targeted lepidopteran insects) than conventional cotton;
- the risk of the Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton establishing as a weed as a result of the proposed release is low and not likely to be greater than that of conventional cotton;
- the risk of development of herbicide-resistant weeds is negligible due to the small scale of the release;
- the likelihood of some gene transfer from the Bollgard II[®] and the Bollgard II[®]/Roundup Ready[®] cotton to cultivated cotton is high, but the overall frequency of out-crossing would be very low. This would not pose any risks additional to those posed by the Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton itself;
- the potential for transfer of the introduced genes to wild or native cotton is functionally zero because of the geographical isolation and genetic incompatibility with the native species;

- the likelihood of transfer of the introduced genes to organisms other than cotton is negligible, but even if such transfer occurred would be unlikely to pose any hazard to human health and safety or the environment; and
 - the risk of development of target insects resistant to the insecticidal proteins is negligible due to the small scale of the release.
- **Agronomic Assessment and Seed Increase of Transgenic Cotton Expressing Tolerance to the Herbicide Glufosinate Ammonium (DIR 015)**

The CSIRO has applied for a licence for the limited and controlled release (field trial) of a GM herbicide-tolerant cotton, known as Liberty[®] cotton, into the environment.

Liberty[®] cotton contains the *bar* gene from a common soil bacterium that encodes the enzyme phosphinothricin acetyl transferase (PAT) that confers tolerance to the herbicide glufosinate ammonium, the active constituent of Basta[®], Liberty[®] and a number of other herbicides. The *bar* gene was also used as a marker during the genetic modification process to enable selection in the laboratory of plants containing the desired modification.

CSIRO is proposing to carry out a limited release on one site, in the shire of Narrabri (NSW), over a total area of up to 2 hectares. None of the cotton plants from the proposed release, or their by-products, would be used for human food or animal feed. However, the applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

GTTAC considered the RARMP for this application. The Regulator was advised that the Committee agreed with the conclusions of the risk assessment and endorsed the proposed risk management plan, which included the following licence conditions:

- an isolation zone of 50 metres in all directions from the outer edge of the pollen trap;
 - the outer edge of the pollen trap should not be within 50 metres of natural waterways;
 - any viable material not required for subsequent releases should be destroyed; and
 - the release should be monitored for a period of twelve months after the release and the volunteers removed.
- **Evaluation under Field Conditions of Sub-clover Stunt Virus Promoters Driving an Insect Tolerance Gene (*Cry1Ab*) from *Bacillus thuringiensis* (DIR 016)**

CSIRO has applied for a licence for the limited and controlled release (field trial) of GM insecticidal/herbicide-tolerant cotton into the environment. The main aim of the proposed release is to assess the relative activity of different promoters by measuring the insecticidal activity of the cotton. A promoter is a piece of DNA that determines whether or not a gene is expressed, and to what extent. The applicant states that this GM cotton is not intended for commercial release.

The GM cotton contains an insecticidal protein that makes the cotton resistant to lepidopteran caterpillar pests. Expression of the *Cry1Ab* gene encoding the insecticidal protein is driven by promoters derived from plant viruses.

The GM cotton also contains the *bar* gene from a common soil bacterium, which encodes a protein that confers tolerance to glufosinate ammonium, the active constituent in Basta[®], Liberty[®] and a number of other herbicides. This herbicide tolerance gene was used as a marker during the genetic modification process, to enable selection in the laboratory of plants containing the desired modification.

CSIRO is proposing to carry out a limited release of approximately 60 different cotton lines, representing different transformation events. The release would be carried out on a total area of 1.5 hectares on two sites in the shire of Narrabri (NSW). None of the cotton plants from the proposed release, or their by-products, would be used for human food or animal feed. However, the applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

GTTAC considered the RARMP for this application and agreed that the risk assessment adequately identified the risks associated with this proposal, however the Committee suggested that further information on the activity of the stunt7 and stunt4 virus promoters could be included.

GTTAC endorsed the risk management plan, and advised the Regulator that similar licence conditions to those proposed for DIR 015 would be appropriate for this application.

- **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 (field trial) of GM insecticidal cotton into the environment. The main aim of the proposed release is to assess the agronomic performance and the insecticidal activity of the GM cotton. CSIRO also proposes to produce seed from selected lines for possible future releases, which would be subject to separate applications and assessment processes.

Details of the gene construct, including the identity of the insecticidal gene, the antibiotic resistance gene and the identity/origin of the regulatory sequences, as well as the specific cultivars proposed for release, have been declared as Confidential Commercial Information (CCI) under Section 185 of the *Gene Technology Act 2000*. However, this information was made available to GTTAC and the other prescribed expert authorities that were consulted on the RARMP.

The GM cotton contains a gene that produces an insecticidal protein derived from *Bacillus thuringiensis*, a common soil bacterium, which makes the cotton resistant to lepidopteran caterpillar pests. The protein is different from insecticidal proteins derived from genes of the same bacterium that are present in other types of GM cotton available commercially or currently being trialed in Australia. The new gene may provide additional options to manage the risk of development of insect resistance to the other insecticidal proteins.

Some of the GM cotton also contains an antibiotic resistance gene, from the bacterium *Escherichia coli*. The antibiotic resistance gene was used as a marker during the genetic modification process, to enable selection in the laboratory of plants containing the desired modification.

CSIRO is proposing to carry out a limited release on three sites in the shires of Narrabri and Moree Plains (NSW), over a total area of 3 hectares. None of the cotton plants from the proposed release, or their by-products, would be used for human food or animal

feed. However, the applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

GTTAC considered the RARMP for this application. The Committee endorsed the risk management plan and advised the Regulator that similar licence conditions to those proposed for DIR 015 would be appropriate for this application.

Advice on Cotton Applications

- **Commercial Release of INGARD[®] Cotton Event 531 in Australia (DIR 022)**

The OGTR has received a licence application from Monsanto for the intentional release of INGARD[®] cotton into the environment in the cotton growing regions of NSW and Qld south of latitude 22° South. Approval would enable the continued commercial release of the GM cotton. Monsanto also proposes the phasing-out of INGARD[®] cotton over the next three years while Bollgard II[®] cotton (which was approved for commercial release in September 2002, DIR 012/2002) is phased-in over the same period.

INGARD[®] cotton is resistant to lepidopteran caterpillar pests that attack cotton. It contains an insecticidal gene, *Cry1Ac*, derived from the soil bacterium *Bacillus thuringiensis*, that produces a protein that is toxic to specific insects.

It is intended that the GM cotton plants and their by-products, including cottonseed, be used in the same manner as conventional cotton, including for human food and stockfeed. Cottonseed is processed for oil that is used in a variety of food products and for cotton linters (a type of fibre that does not contain any genetic material) that are used as a cellulose base for several consumer food products. Food Standards Australia New Zealand, FSANZ, (formerly the Australia New Zealand Food Authority, ANZFA) has already approved the use of oil and linters from INGARD[®] cotton in human food.

The applicant seeks approval for commercial release of the GM cotton in all Australian cotton growing regions south of latitude 22° South, and no limitations on transportation or storage are proposed (see below for further explanation). However, the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) will remain responsible for determining the total planting area of INGARD[®] cotton each season. The NRA currently only allows up to 30% of the cotton crop to be planted to this GM cotton to guard against the emergence of resistant insects.

GTTAC discussed this application and advised the Regulator that the following matters should be considered in the preparation of the RARMP:

- monitoring dairies and their immediate surrounds for the presence and destruction of volunteers in northern Australia (above latitude 22° S);
- double bagging, or covering of GM cotton seed and seed material by tarpaulins while being transported in areas above latitude 22° South;
- approaching the Cotton Research and Development Corporation to conduct research into gene flow and environmental impacts of GM cotton; and
- conformance with any conditions set by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA).

GTTAC further advised the Regulator that the licence conditions proposed for a previous cotton application (DIR 012/2002) could also apply to this proposal.

- **Commercial Release of Roundup Ready® Cotton Event 1445 (DIR 023)**

The OGTR has received a licence application from Monsanto for the intentional release of Roundup Ready® and Roundup Ready®/INGARD® cotton into the environment in the cotton growing regions of NSW and Qld, south of latitude 22° South. Approval would enable the continued commercial release of the GM cotton. Monsanto also proposes the phasing-out of Roundup Ready®/INGARD® cotton over the next three years while Roundup Ready®/Bollgard II® cotton (which was approved for commercial release in September 2002; DIR 012/2002) is phased-in over the same period.

Roundup Ready® cotton contains a gene that provides tolerance to glyphosate, the active ingredient of the herbicide Roundup®. Conventional cotton is susceptible to glyphosate. The use of Roundup Ready® cotton allows the application of Roundup® for the control of weeds that emerge in the crop. Roundup Ready®/INGARD® cotton was produced by conventional breeding of Roundup Ready® cotton with INGARD® cotton. The Roundup Ready®/INGARD® cotton inherits an insecticidal gene from INGARD® cotton that produces a protein toxic to lepidopteran caterpillar pests.

It is intended that GM cotton plants and their by-products, including cottonseed, be used in the same manner as conventional cotton, including for human food and stockfeed. Cottonseed is processed for oil that is used in a variety of food products and for cotton linters (a type of fibre that does not contain any genetic material) that are used as a cellulose base for several consumer food products. FSANZ has approved the use of oil and linters from Roundup Ready®, INGARD® and Bollgard II® cotton in human food.

The applicant seeks approval for commercial release of the GM cotton in all Australian cotton growing regions south of latitude 22° South, without limitations on transportation and storage in northern Australia.

GTTAC discussed this application and advised the Regulator that the issues to be considered in the preparation of the RARMP were the same as for the previous application (DIR 022).

- **Seed Increase and Efficacy Studies in Northern Australia of Transgenic Cotton Expressing *Cry1Ac* or *Cry 1Ac* and *Cry 2Ab* (DIR 024)**

CSIRO has applied for a licence for the limited and controlled release (field trial) into the environment of transgenic cotton expressing insecticidal and/or herbicide tolerance genes.

The proposed release aims to evaluate agronomic performance and seed increase of GM cottons in northern Australia. The agronomic studies would involve growing INGARD®, Bollgard II® and Bollgard II®/Roundup Ready® cotton. In addition, the release will collect information on the environmental impacts of the GM cotton. Effects of the GM cotton on the type and abundance on pest and beneficial insects, the potential development of insects resistant to the insecticidal activity of the GM cotton and the potential weediness of GM cotton in the northern environment will be studied.

INGARD® and Bollgard II® cotton are resistant to the lepidopteran caterpillar pests that attack cotton. They contain one or two insecticidal genes, respectively, that produce proteins that are toxic to specific insects. Bollgard II®/Roundup Ready® cotton also contains a gene for tolerance to the herbicide, glyphosate (Roundup®).

CSIRO proposes to carry out a limited release at five sites, Katherine and Douglas Daly in the Northern Territory and at Kununurra in Western Australia, over a total area of 136.5 hectares. None of the cotton plants from any of the trials, or their by-products, will be used for human food. The applicant proposes to transport the INGARD[®] cottonseed from the release for use as cattle feed in the eastern states. All transport and storage would be in accordance with requirements of the OGTR. The applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

GTTAC advised the Regulator that the issues to consider in the preparation of the RARMP are similar to previous GM cotton applications such as DIR 013 and DIR 014.

In addition, GTTAC recommended that an isolation distance be implemented where the cotton is to be planted in close proximity to other cotton crops.

- **Seed Increase and Efficacy Studies in Northern Australia of Transgenic Cotton Expressing a New Insecticidal Protein Gene (DIR 025)**

CSIRO has applied for a licence for the limited and controlled release (field trial) into the environment of GM cotton containing an insecticidal gene.

CSIRO has sought approval for details of the gene construct, and the regulatory sequences (promoters), including the plasmid map, to be declared Confidential Commercial Information (CCI). This aspect of the application is still under consideration, however this information was made available to GTTAC and the other prescribed expert authorities that were consulted on the preparation of the RARMP.

The main aim of the proposed release is to evaluate the agronomic performance of cotton lines modified to express a new insecticidal protein that is toxic to lepidopteran caterpillar pests. The lines also contain an antibiotic resistance marker gene. The release would also be used to produce seed for future releases in an ongoing breeding program (which would be subject to further approvals).

CSIRO proposes to carry out a limited and controlled release on three sites, in the shire of Wyndham-East Kimberley, over a total area of 3 hectares. None of the cotton plants from the release, or their by-products, would be used for animal and human food. However, the applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

GTTAC noted the limited scale of the release and agreed that the issues associated with this application were similar to the previous application (DIR 024). GTTAC advised the Regulator that the issues to consider in the preparation of the RARMP were similar to previous GM cotton applications.

Advice on Poppy

GTTAC considered one RARMP for the release of transgenic poppies in Australia.

Advice on Poppy RARMP

- **Field Assessment of Alkaloids in Modified Poppy (DIR 018)**

CSIRO has applied for a licence for a limited and controlled release (field trial) of GM oilseed poppies (*Papaver somniferum* subsp. *somniferum*) into the environment. Some

details of the gene construct, including the identity of the alkaloid pathway genes, and the identity and origins of the regulatory sequences have been declared as Confidential Commercial Information (CCI) under section 185 of the Act.

A total of eight types of GM oilseed poppy are proposed to be trialed in order to examine the effect of the modifications on alkaloid production under field conditions.

The modifications intend to vary alkaloid production by altering the expression of one of five plant genes that produce proteins that function at different steps in the alkaloid synthesis pathway.

Four of the five modified alkaloid synthesis genes are derived from oilseed poppy, while the fifth is from the related Californian poppy (*Eschscholzia californica*). The expression of each of the introduced genes is under the control of one of two viral promoters and a termination sequence that acts as a 'stop signal' for the expression of the introduced genes.

All of the modified poppies also contain the selectable marker gene *nptII* from the bacterium *Escherichia coli*. The *nptII* gene encodes the enzyme neomycin phosphotransferase II (NPTII) which confers resistance to the antibiotics neomycin, kanamycin, and gentamicin. The *nptII* gene also contains an intron derived from the catalase-1 gene of the castor bean, *Ricinus communis*. The expression of the *nptII* gene is under the control of the cauliflower mosaic virus (CaMV) 35S promoter and termination sequence.

CSIRO is proposing to carry out a limited and controlled field release at one site in the Meander Valley shire, Tasmania. The GM oilseed poppy plantings would comprise an area of 0.064 ha. The GM poppies would be surrounded by a 10 metre pollen trap of non-GM poppies, making up a total trial site area of 0.21ha. None of the oilseed poppy plants from the release or their by-products will be used for human or animal feed, or therapeutics, or for any other commercial use.

GTTAC considered the RARMP for this application and advised the Regulator that the risk assessment adequately addressed the issues associated with this proposal. In consideration of the risk management plan GTTAC suggested that the small size of the release would hamper the applicant's ability to effectively conduct research into gene flow and recommended that this requirement be removed from the licence conditions. GTTAC also advised that, due to lack of evidence of increased alkaloid production by the GM poppies, it may be too early to conduct research into the environmental impact of this trait, as proposed in the application.

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 on 1800 181 030. The RARMPs are also available electronically from our website at <http://www.ogtr.gov.au/publications/riskassessments.htm>
