



**Australian Government**  
**Department of Health and Ageing**  
**Office of the Gene Technology Regulator**

**APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 089**

**SUMMARY INFORMATION**

Project Title:	Limited and controlled release of white clover genetically modified to resist infection by Alfalfa mosaic virus <sup>1</sup>
Applicant:	Victorian Department of Primary Industries
Common name of the parent organism:	White Clover
Scientific name of the parent organism:	<i>Trifolium repens</i> L.
Modified trait(s):	Viral disease resistance, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none"><li>• <i>AMV CP</i> gene from Alfalfa mosaic virus (viral disease resistance)</li><li>• <i>nptII</i> gene from the bacterial Tn5 transposon (antibiotic resistance)</li></ul>
Proposed Location(s):	One site in the shire of Corowa, NSW
Proposed Release Size:	633 m <sup>2</sup>
Proposed Release Dates:	March 2009 - August 2011

**Introduction**

The *Gene Technology Act 2000* (the Act) in conjunction with the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, comprise Australia's nationally consistent regulatory system for gene technology. Its objective is to protect the health and safety of people, and the environment, by identifying risks posed by or as a result of gene technology, and managing those risks by regulating certain dealings with genetically modified organisms (GMOs).

The Act establishes a statutory officer, the Gene Technology Regulator (the Regulator), to administer the legislation and make decisions under the legislation. The Regulator is supported by the Office of the Gene Technology Regulator (OGTR), an Australian Government regulatory agency located within the Health and Ageing portfolio.

The legislation sets out the requirements for considering applications for licences for dealings with GMOs and the matters that the Regulator must take into account before deciding whether, or not, to issue a licence. The Regulator's *Risk Analysis Framework*<sup>2</sup> outlines the assessment process that will be followed.

**Confidential Commercial Information**

Some details, including screening protocols, data from previous field trials and unpublished data produced to support weediness and gene flow assessments, have been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information will be

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<sup>1</sup> The title of the licence application submitted by DPI Victoria is 'Field evaluation of agronomic performance and seed yield assessment for white clover transformed to resist infection by Alfalfa mosaic virus'.

<sup>2</sup> More information on the assessment of licence applications is available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au>>.

made available to the prescribed experts and agencies that will be consulted on the RARMP for this application.

## The application and the proposed dealings

The Acting Regulator has received an application from DPI Victoria for a licence for dealings involving the intentional release of genetically modified (GM) white clover (*Trifolium repens* L.) into the Australian environment on a limited scale under controlled conditions.

One line<sup>3</sup> of GM white clover is proposed for release. The GM white clover contains the Alfalfa mosaic virus coat protein gene (*AMV CP*) intended to provide resistance to Alfalfa mosaic virus (AMV), and an antibiotic resistance gene (*nptII*) which provides resistance to the antibiotic kanamycin.

The purpose of the trial is to conduct experiments to evaluate the agronomic performance, including seed yield, of the GM white clover line under field conditions. Some seed will be retained for seed increase or further experimentation (subject to additional approvals).

The applicant proposes to limit the release to one site in the local government area of Corowa, NSW, on a maximum area of 633 m<sup>2</sup> between March 2009 and August 2011.

The applicant has also proposed a number of control measures to restrict the dissemination or persistence of the GM plants and their introduced genetic material that will be considered in the assessment of this application including:

- locating the trial site more than 280 m away from natural waterways;
- surrounding the release site by both a livestock-proof and a rabbit-proof fence to reduce seed dispersal by grazing animals;
- surrounding the GM white clover plot by a pollen trap, consisting of an inner one metre wide band of non-GM white clover, surrounded by a band of lucerne at least 35 metres wide, and an outer one metre wide band of non-GM white clover;
- monitoring the GM clover fortnightly during flowering, and removal of flowers from the GM white clover plants in the event of the pollen trap plants not flowering simultaneously;
- monitoring the lucerne band monthly and destroying any white clover plants prior to flowering;
- monthly monitoring for, and destroying any, white clover plants that may occur within 500 metres of the release site;
- removal of mature flower heads during peak flowering time to reduce the build-up of a seed bank;
- not permitting any materials from the release to be used in human food or animal feed
- specific containment, transport and storage conditions in accordance with OGTR guidelines;
- cleaning the site after trial through herbicide application and topping (seed head removal);
- destroying all GM plant material not required for testing or future trials;
- placing a footbath and washbasin at gate of release site to clean all implements; and
- monitoring for, and destroying any, volunteer GM white clover that may occur in the release area for five years after completion of the trial.

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<sup>3</sup> The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

## Parent organism

The parent organism is white clover (*Trifolium repens* L.), which is exotic to Australia and is grown as a component of improved pastures in south-eastern Australia and in the wetter parts of Western Australia. It is the dominant pasture clover for the Australian dairy industry. The three white clover cultivars used to produce the GMOs proposed for release are Irrigation, Mink and Grasslands Sustain.

## The genetic modifications and their effect

The GM white clover line contains the coat protein gene from AMV, which is expected to reduce the susceptibility of the clover plants to AMV. Evaluation in contained facilities and previous field trials showed *AMV CP* gene expression and virus resistance in the GM white clover line proposed for release in this field trial. The GM white clover plants also contain a selectable marker gene (*nptII*) which confers resistance to aminoglycoside antibiotics related to kanamycin and neomycin.

Short regulatory sequences that control expression of the gene are also present in the GM white clover. These are derived from Cauliflower mosaic virus (CaMV) and pea. Although some of these sequences are derived from a plant pathogen (CaMV), the regulatory sequences comprise only a small part of the pathogen's total genome, and are not in themselves capable of causing disease.

## Method of genetic modification

The coat protein gene, *nptII* gene and associated regulatory sequences were originally introduced into the white clover cultivar Irrigation on a plasmid vector carried by *Agrobacterium tumefaciens* (a common soil bacterium). The vector is 'disarmed' since it lacks the genes that encode the tumorigenic functions of *A. tumefaciens*. The GM plants produced from one transformation event were conventionally bred with the white clover cultivars Mink and Grasslands Sustain to produce the GMO for the proposed release. Plants containing a single insertion of the *AMV CP* gene in a homozygous state will be used in this proposed field trial.

## Previous releases of the same or similar GMOs

The GM white clover line proposed for release in this application has been previously approved for release under DIR 047/2003 (DPI Victoria), and was the subject of four earlier releases under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC), (PR-64, PR-64X, and PR-64X2 by LaTrobe University and PR-67 by CSIRO, Plant Industry). The size of the releases ranged from 494 m<sup>2</sup> to four hectares.

There have been no reports of adverse effects on human health and safety or the environment resulting from these releases.

## Suitability of Applicant

Section 43(2)(f) of the Act requires the Regulator to be satisfied regarding the suitability of the applicant to hold a licence as a pre-requisite for considering DIR applications. The matters to be considered are outlined in Section 58 of the Act and include relevant convictions, revocation of a licence or permit relating to the health and safety of people, and capacity to meet the conditions of the licence.

The Acting Regulator has determined that DPI Victoria currently meets the suitability requirements and will verify this continues to be the case prior to making any decision regarding the issuing of a licence.

## Consultation process for this DIR application

The Acting Regulator has made an assessment of whether the application should be considered as a limited and controlled release, under section 50A of the Act. As its principal purpose is to enable the conduct of experiments, and the applicant has proposed limits on the size and duration of the

release and controls to restrict the dissemination and persistence of both the GMO and its genetic material in the environment, **the Acting Regulator has decided that the application qualifies as a limited and controlled release.**

This means that the Acting Regulator is not required to consult on the assessment of this application until after a Risk Assessment and Risk Management Plan (RARMP) has been prepared in accordance with section 51 of the Act. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 089.

The Acting Regulator will seek comment on the consultation RARMP from the public as well as a wide range of experts, agencies and authorities including the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies and the Minister for the Environment, Heritage and the Arts. The RARMP will then be finalised, taking into account matters raised relating to risks to human health and safety and the environment, and form the basis of her decision whether or not to issue a licence.

At this stage, **the RARMP is expected to be released for comment in October 2008.** The public will be invited to provide submissions on the RARMP via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. The RARMP and other related documents will be available on the OGTR website, or in hard copy from the OGTR.

If you have any questions about the application or the assessment process, or wish to register on the mailing list, please contact the OGTR at:

**The Office of the Gene Technology Regulator, MDP54 GPO Box 9848 Canberra ACT 2601**

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