



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 082/2007

SUMMARY INFORMATION

Project Title:	Limited and controlled release of perennial ryegrass and tall fescue genetically modified for improved forage qualities ¹
Applicant:	Victorian Department of Primary Industries (DPI Victoria)
Common name of the parent organisms:	Perennial ryegrass and tall fescue
Scientific name of the parent organisms:	<i>Lolium perenne</i> L., <i>Lolium arundinaceum</i> Schreb ² .
Modified trait(s):	Improved forage qualities (altered carbohydrate levels or plant cell structure)
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• three genes from perennial ryegrass (altered carbohydrate levels)³• nine genes from perennial ryegrass or tall fescue (altered plant cell structure)• <i>hph</i> gene (hygromycin resistance marker)
Proposed Location(s)	One site in the Southern Grampians Shire, Victoria
Proposed Release Size:	800m ²
Proposed Release Dates:	June 2008 to July 2010

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

¹ The title of the licence application submitted by DPI Victoria is *Field evaluation of vegetative perennial ryegrass (Lolium perenne L.) and vegetative tall fescue (Lolium arundinaceum) plants expressing fructan or lignin metabolism genes.*

² *Lolium arundinaceum* is the current name for the grass often referred to as *Festuca arundinacea*

³ Some details of the genetic modifications have been declared CCI under section 185 of the Act

issue a licence. The Regulator's *Risk Analysis Framework*⁴ outlines the assessment process that will be followed.

The application and the proposed dealings

The Regulator has received a licence application from the Victorian Department of Primary Industries (DPI Victoria) for a licence for dealings involving the intentional release of genetically modified (GM) perennial ryegrass (*Lolium perenne* L.) and tall fescue (*Lolium arundinaceum* Schreb.) into the Australian environment on a limited scale under controlled conditions.

Up to 500 GM perennial ryegrass and tall fescue lines⁵ are proposed for release. Each line contains one or more of 12 genes derived from perennial ryegrass and tall fescue. Expression of the introduced genes is expected to improve forage qualities by changing carbohydrate levels and improving digestibility of these pasture grasses.

The purpose of the proposed release is to conduct proof of concept experiments to assess the agronomic performance and forage qualities of the GM lines grown under field conditions. GM plants will be transferred from the trial site to a PC2 glasshouse prior to flowering for controlled breeding experiments. Some seed will be saved for possible future trials (subject to further approvals). The GM perennial ryegrass and tall fescue plants will not be used for human food or animal feed.

The applicant proposes to limit the release to one site in the shire of Southern Grampians, Victoria on a total area of 800m² between June 2008 and July 2010.

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:

- surrounding the 800m² trial site with a border of *Triticale* species
- restricting access to the trial site with a 1 m high fence with a locked gate
- planting at a time when other grasses in the release area are not flowering
- ensuring that the trial site and border rows are free of pasture grasses
- transferring GM plants to a PC2 glasshouse prior to flowering
- analysing GM plant materials in a certified PC2 facility and then destroying the unwanted materials
- destroying all (GM and non-GM) plant materials remaining at the field site by spraying with herbicide
- post harvest monitoring of the trial site for 12 months and destroying any volunteers
- transporting GM plant materials to and from the proposed trial site in accordance with OGTR transportation guidelines
- not using the GMO in human food or animal feed.

Confidential Commercial Information

Some details, including the names of the introduced genes, promoters and terminators expected to alter fructan carbohydrate levels and plant cell structure, and the identity of the cultivars which have been transformed, have been declared Confidential Commercial Information (CCI) under section

⁴ Available on the Office of the Gene Technology Regulator (OGTR) website at <<http://www.ogtr.gov.au/pubform/riskassessments.htm>>. Information on the assessment of licence applications is also available at <<http://www.ogtr.gov.au/ir/process.htm>> or Freecall 1800 181 030.

⁵ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

185 of the Act. The confidential information will be made available to the prescribed experts and agencies that will be consulted on the Risk Assessment and Risk Management Plan (RARMP) for this application.

Parent organism

The parent organisms are perennial ryegrass (*Lolium perenne* L.) and tall fescue (*Lolium arundinaceum* Schreb.), which are exotic to Australia.

Perennial ryegrass is widely cultivated in temperate regions of Australia. It is the dominant forage grown in improved pastures in Australia and is also used for recreational turf. It is genetically distinct from annual ryegrass (*Lolium rigidum*). Tall fescue is widely grown in Australia as a pasture grass and is used for lawns and recreational turf.

The genetic modifications and their effect

Up to 250 of the GM perennial ryegrass lines proposed for release contain one or more of three introduced perennial ryegrass genes encoding proteins involved in fructan biosynthesis in 15 different combinations. The expression of these genes is expected to alter the level of fructan carbohydrates in the GM plants to increase available energy and enhance animal productivity.

Up to 250 lines of GM perennial ryegrass and GM tall fescue are also proposed for release. Each contains one or more of nine introduced genes from perennial ryegrass or tall fescue encoding proteins involved in lignin metabolism in 15 different combinations. The expression of these genes is expected to alter lignin metabolism in the GM plants to increase cell wall digestibility and enhance animal productivity.

The GM perennial ryegrass and tall fescue lines also contain an antibiotic resistance marker gene, *hph*, from the bacterium, *Escherichia coli*. The *hph* gene encodes hygromycin phosphotransferase and was used to select for modified plants in the laboratory. Hygromycin will not be applied to the plants during the proposed field trial. While the *hph* gene is derived from a bacterium capable of causing illness in humans, the *hph* gene comprises only a small part of the *E. coli* genome and is not capable of causing disease.

The GM perennial ryegrass and tall fescue lines also contain short regulatory sequences derived from plant or animal pathogens (Cauliflower mosaic virus and *E. coli*, respectively) and/or plants, (*Lolium perenne* - perennial ryegrass, *Lolium arundinaceum* - tall fescue, *Zea mays* – maize, *Triticum aestivum* -wheat and *Oryzae sativa* -rice). The regulatory sequences from plant or animal pathogens comprise only a small part of their total respective genome and are not capable of causing disease.

Method of genetic modification

Biolistic transformation, also known as particle bombardment, was used to produce the GM perennial ryegrass and tall fescue lines. This technique involves coating the expression cassette containing the gene constructs onto very small gold particles that are ‘shot’ into tissue of perennial ryegrass or tall fescue. Particle bombardment has been widely used in Australia and overseas for introducing new genes into plants without causing any safety concerns.

Transformed plant tissues were identified using the expression of the marker gene and grown into plants in the laboratory. Molecular analysis was used to confirm the presence of the gene(s) of interest in the individual plants that were selected to produce the GM lines.

Previous releases of the same or similar GMOs

There have been no previous releases of these GM perennial ryegrass and tall fescue lines or any other GM perennial ryegrass and tall fescue in Australia.

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 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 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 Regulator has decided that the application qualifies as a limited and controlled release.**

This means that the 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 082/2007.

The 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 and relevant local councils. 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 late May 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

MDP 54

GPO Box 9848

Canberra ACT 2601

Tel: 1800 181 030

Fax: 02 6271 4202

Email: ogtr@health.gov.au

Website <http://www.ogtr.gov.au>