



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 084/2008

SUMMARY INFORMATION

Project Title:	Limited and controlled release of torenia genetically modified for enhanced phosphate uptake ¹
Applicant:	Florigene Pty Ltd (Florigene)
Common name of the parent organism:	Torenia
Scientific name of the parent organism:	<i>Torenia x hybrida</i>
Modified trait(s):	Enhanced phosphate uptake, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• PHR1 (phosphate starvation response regulator 1) from <i>Arabidopsis thaliana</i>• nptII (neomycin phosphotransferase type II) from <i>Escherichia coli</i> (antibiotic resistance selectable marker)
Proposed Location(s)	One site in the City of Darebin, Victoria
Proposed Release Size:	Up to 400 plants in an area not exceeding 20m ²
Proposed Release Dates:	October 2008 to May 2009

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 Florigene is *Outdoor trial of torenia genetically modified with the PHR1 gene*

issue a licence. The Regulator's *Risk Analysis Framework*² outlines the assessment process that will be followed.

The application and the proposed dealings

The Regulator has received a licence application from Florigene Pty Ltd (Florigene) for a licence for dealings involving the intentional release of genetically modified (GM) torenia (*Torenia x hybrida*) into the Australian environment on a limited scale under controlled conditions.

Three lines³ are proposed for release. Each line contains the *PHR1* gene from thale cress (*Arabidopsis thaliana*) under the control of a different promoter. Expression of the introduced gene is expected to enhance the capacity of the GM torenia plants to absorb phosphate from polluted water.

The proposed trial would involve growing the GM plants hydroponically to conduct experiments to assess the capacity of the different lines to absorb phosphate and slow or repress algal overgrowth in the surrounding water.

The applicant intends to limit the release to a maximum of 400 plants at one site not exceeding 20m² in the City of Darebin, Victoria, from October 2008 to May 2009.

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 within the perimeter of existing Florigene greenhouse infrastructure, which is surrounded by a 2.1 metre fence and lockable gates;
- growing the plants hydroponically at ground level in 1000 litre plastic tubs;
- monitoring the trial site on a biweekly basis and as soon as possible after severe weather;
- destroying all plant materials not required for laboratory analysis;
- post harvest monitoring of the trial site and destroying any volunteers;
- transporting GM plant materials in accordance with OGTR transportation guidelines; and
- not using the GMO in human food or animal feed.

Confidential Commercial Information

The identity of one of the promoters used to control expression of the introduced gene in one of the three GM torenia lines has been declared Confidential Commercial Information (CCI) under section 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 organism is the ornamental flowering plant, *Torenia x hybrida* (cv. Summerwave® blue), which is exotic to Australia but commercially available for planting in home gardens. *T. x hybrida* was specifically bred as a pot plant and is a sterile hybrid that does not set seed or produce viable pollen.

² 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.

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

The genetic modifications and their effect

The three GM torenia lines contain the phosphate signalling response gene, *PHR1*, which encodes a transcription factor⁴ thought to play a role in plant responses to phosphate deficiency. The *PHR1* gene was derived from thale cress (*Arabidopsis thaliana*), which is an important experimental species for studying plant biology. Expression of the introduced gene is expected to enhance the capacity of the GM torenia plants to absorb phosphate.

In addition, all of the GM torenia lines contain the antibiotic resistance gene, *neomycin phosphotransferase type II (nptII)*. This gene, encoding the enzyme neomycin phosphotransferase, was derived from the common gut bacterium, *Escherichia coli*, and confers kanamycin or neomycin resistance on the GM plant. The *nptII* gene was used as a selective marker to identify transformed plants during initial development of GM plants in the laboratory.

Short regulatory sequences that control expression of the introduced gene are also present in the GM torenia lines. Although derived from pathogenic sources (e.g. cauliflower mosaic virus and the common soil bacterium, *Agrobacterium tumefaciens*), the regulatory sequences comprise only a small part of their total respective genome, and are not capable of causing diseases.

Method of genetic modification

Individual gene constructs were introduced into plant tissues of *T. x hybrida* by *Agrobacterium tumefaciens*-mediated transformation. The constructs are 'disarmed' since they lack the genes that encode the tumorigenic functions of *A. tumefaciens*. This method has been widely used in Australia and overseas for introducing new genes into plants and is not known to cause any adverse effects for people or the environment. Transformed torenia plants were grown in tissue culture in the laboratory and molecular analysis confirmed the presence of the *PHR1* gene. Each GM torenia line resulted from an independent transformation event with one gene construct.

Previous releases of the same or similar GMOs

There have been no previous releases of these GM torenia lines in Australia. GM torenia lines with altered flower colour, derived from *T. x hybrida*, were previously approved for limited and controlled release under Licence DIR 068/2006.

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 Florigene 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

⁴ A transcription factor is any protein required for the recognition, by RNA polymerases, of specific regulatory sequences in genes (e.g. a promoter)

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 084/2008.

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, and the relevant local council(s). 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 early July 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>