



APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 090

SUMMARY INFORMATION

Project Title:	Commercial release of rose genetically modified for altered flower colour
Applicant:	Florigene Pty Ltd
Common name of the parent organism:	Hybrid Tea rose
Scientific name of the parent organism:	<i>Rosa x hybrida</i>
Modified trait(s):	<ul style="list-style-type: none">• Altered flower colour• Antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• <i>Flavonoid 3'5'-hydroxylase (F3'5'H)</i> gene from <i>Viola tricolor</i> (flower colour)• <i>Anthocyanin 5-acyltransferase (5AT)</i> gene from <i>Torenia x hybrida</i> (flower colour)• <i>nptII</i> gene from the Tn5 transposon of <i>Escherichia coli</i> (antibiotic resistance)
Proposed Location(s):	Australia wide
Proposed Release Size:	N/A Propagation/growing of plants at one or more locations in Australia and sale of cut flowers throughout Australia
Proposed Release Dates:	Ongoing from date of approval

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*¹ outlines the assessment process that will be followed.

¹ 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/internet/ogtr/publishing.nsf/Content/process-1>>.

Confidential Commercial Information

An application for Confidential Commercial Information (CCI) under section 185 of the Act is still under consideration for some information in the application regarding a study of wild *Rosa* spp. This information will be available to the prescribed experts and agencies that will be consulted on the preparation of the Risk Assessment and Risk Management Plan (RARMP) for this application.

The application and the proposed dealings

The Acting Regulator has received an application from Florigene Pty Ltd (Florigene) for a licence for dealings involving the intentional release of genetically modified (GM) Hybrid Tea rose (*Rosa x hybrida*) into the Australian environment.

One line² of GM rose is proposed for release. The GM rose contains two genes that are derived from flowering plants and have been shown to alter flower colour from pink to purple/blue. In addition, the line contains an antibiotic resistance gene that provides resistance to the antibiotic kanamycin and was used for the selection of transformed plants in the laboratory.

The purpose of the release is the propagation of parent plants and the growing of plants for cut flowers, and the release would be ongoing from the time of approval, if such approval were to be granted. Florigene intends to grow GM rose plants and handle their products (i.e. cut flowers) in the same manner as for conventional rose plants. Parent plants and plants for cut flowers would be grown by growers registered with Florigene. Flowers that are produced would be sold through normal commercial distribution channels to the public, Australia-wide.

Parent organism

The parent organism is a Hybrid Tea rose (*Rosa x hybrida*) line, that is exotic to Australia and is grown horticulturally both as an ornamental in gardens/landscapes and as a source of cut flowers for the floriculture industry. While two *Rosa* spp. have escaped from cultivation and become classed as noxious weeds in Australia, there are no reports of Hybrid Tea roses becoming naturalized despite more than 100 years of cultivation.

The genetic modifications and their effect

The GM rose line contains two genes, the *Flavonoid 3'5'-hydroxylase (F3'5'H)* gene from *Viola tricolour* and the *Anthocyanin 5-acyltransferase (5AT)* gene from *Torenia x hybrida*, that are expressed in the epidermal layer of flower petals and cause the production of delphinidin pigments that confer a blue hue on the flowers. Non-GM roses do not normally have blue flowers since the enzymes responsible for the production of delphinidin are lacking. The GM rose plants also contain a selectable marker gene (*nptII*) which confers resistance to aminoglycoside antibiotics related to kanamycin and neomycin. The GM line is a periclinal chimera and the pollen that is produced does not contain the introduced genes.

Short regulatory sequences that control expression of the genes are also present in the GM rose. These are derived from Cauliflower mosaic virus (CaMV), Tobacco mosaic virus (TMV) and *Agrobacterium tumefaciens*. Although all of these sequences are derived from plant pathogens, 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 genes influencing flower colour, the *nptII* gene and associated regulatory sequences were originally introduced into the Hybrid Tea rose line WKS82 on a plasmid vector carried by *Agrobacterium tumefaciens* (a common soil bacterium). The *A. tumefaciens* is 'disarmed' since it lacks

² The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

the genes that encode tumorigenic functions. This method has been widely used in Australia and overseas for introducing new genes into plants.

Transformed plant tissues were identified using the expression of the antibiotic resistance marker gene and grown into plants in the laboratory.

Previous releases in Australia of the same or similar GMOs

The GM rose line proposed for commercial release is one of three lines that were previously approved for a limited and controlled release (DIR 060/2005) by the Regulator. There have been no reports of adverse effects on human health and safety or the environment resulting from this limited and controlled release.

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 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

Since this application is for commercial purposes, it cannot be considered as a limited and controlled release application under section 50A of the Act.

This means that the Acting Regulator is required to seek advice from prescribed experts, agencies and authorities on matters relevant to the Risk Assessment and Risk Management Plan (RARMP) that must be prepared, in accordance with section 51 of the Act. This first round of consultation must include the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies, any local council that the Regulator considers appropriate and the Minister for the Environment, Heritage and the Arts. While the Regulator is not required to seek public comment at this stage, copies of the application are available on request from the OGTR.

In a second round of consultation, the Acting Regulator will then seek comment on the consultation RARMP from the public as well as prescribed experts, agencies and authorities. The RARMP will 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 consultation version of the RARMP is expected to be released for comment in **March 2009**. 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

Telephone: 1800 181 030 Facsimile: 02 6271 4202 E-mail: ogtr@health.gov.au

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