



APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 060/2005
SUMMARY INFORMATION

Project Title:	Propagation and trial of imported GM rose varieties
Applicant:	Florigene Limited Collingwood VIC 3066
Common name of the parent organism:	Rose
Scientific name of the parent organism:	<i>Rosa x hybrida</i>
Modified trait(s):	Altered flower colour, selectable marker
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• gene encoding flavonoid 3', 5' hydroxylase (F3'5'H) from black pansy (<i>Viola tricolor</i>)• gene encoding anthocyanin 5-acyltransferase from torenia (<i>Torenia hybrida</i>)• gene encoding dihydroflavonol reductase (DFR) from Iris (<i>Iris hollandica</i>)• partial antisense/sense of gene encoding dihydroflavonol reductase (DFR) from rose• <i>nptII</i> gene from <i>Escherichia coli</i> (selectable marker)
Proposed Location(s)	One site in the Shire of Yarra Ranges, Victoria
Proposed Release Size:	100 m ² (0.01 ha)
Proposed Release Dates:	March 2006 to April 2008

Introduction

The *Gene Technology Act 2000* (the Act) took effect on 21 June 2001. The Act, supported by the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, underpins 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 application and the proposed dealings

The OGTR has received an application from Florigene Limited (Florigene) for a licence for the intentional release of genetically modified (GM) *Rosa x hybrida* (rose) into the environment on a limited scale and under controlled conditions.

Three GM rose lines are proposed for release. They are hybrid tea and floribunda rose varieties which have been genetically modified by insertion of genes affecting the synthesis of blue coloured anthocyanin pigments, leading to altered flower colour. The release is proposed to take place within a greenhouse at one site in Victoria, for up to two years from commencement.

Florigene's aims for the proposed release are to: evaluate the performance of the imported GM rose lines in a semi-contained Australian facility; conduct limited propagation; and generate data to support a possible future application for commercial release. About 100 plants of each GM rose line are proposed for release, along with about 100 plants each of the two non-GM parental rose varieties.

The applicant has proposed the following containment measures:

- The proposed release will be within a free standing greenhouse of framed heavy duty plastic, with a soil floor
- Entry into the greenhouse will be through a sliding door
- Ventilation into the greenhouse will be insect proofed
- The GM roses will be grown in pots using a hydroponic system above soil level
- The floor will be kept free of weeds
- All flowers will be cut for laboratory analysis or destruction, preventing seed set.

At the end of the trial, the applicant proposes to dispose of the plant materials and other waste from the release by composting at the facility.

Previous releases of the GMOs

There has been no previous release of these GM rose lines in Australia.

Parent organism

The parent organism is rose (*Rosa x hybrida*) of the Hybrid Tea or Floribunda types. *Rosa x hybrida* is not a species in the botanical sense, but is a description used for most cultivated rose cultivars. These cultivated roses have been derived over centuries through complex crosses involving a number of species of the genus *Rosa*.

Roses are not native to Australia but have a long history of cultivation. Hybrid Tea and Floribunda type roses are grown by commercial flower growers for the cut-flower market and for domestic and industrial landscaping. As well as *Rosa x hybrida*, a number of *Rosa* species also have been introduced into Australia as ornamentals. Some have become naturalised or are considered to be weeds. However *Rosa x hybrida* varieties have not become naturalised nor are they considered to be weeds.

Genetic modification and its effect

The three GM rose lines proposed for release have each been modified using one of two combinations of introduced genes affecting anthocyanin synthesis.

Anthocyanins are the principle class of pigments responsible for flower colour. There are three groups of anthocyanins having different colour ranges. Roses do not naturally make the blue group of anthocyanins (delphinidins), as they lack a key enzyme required for their synthesis, flavonoid 3', 5' hydroxylase (F3'5'H).

All of the GM rose lines contain an introduced gene encoding the F3'5'H gene from *Viola tricolor* (black pansy). Two of the lines also contain a gene encoding anthocyanin 5-acyltransferase from torenia (*Torenia hybrida*), which modifies the delphinidin produced.

The third GM rose line contains, in addition to the *Viola* F3'5'H gene, an introduced gene encoding dihydroflavonol reductase (DFR) from iris (*Iris hollandica*), and introduced sequences from the DFR gene of rose (*Rosa x hybrida*) designed to prevent expression of the endogenous rose DFR gene. DFR acts at a later step in the synthesis of delphinidins and of other anthocyanins. The iris DFR has higher affinity for intermediates in the pathway of delphinidin synthesis than does the rose DFR.

The antibiotic resistance *nptII* gene from *Escherichia coli* has also been inserted into each of the GM rose lines as a selectable marker.

Some regulatory sequences transferred to the GM rose plants are derived from plant pathogens (cauliflower mosaic virus and *Agrobacterium tumefaciens*). However, they represent only a very small proportion of the pathogen's genome and the sequences are not, in themselves, infectious or pathogenic. Another regulatory sequence transferred to the GM rose plants is derived from petunia.

Method of genetic modification

The genes were introduced into the GM rose lines on plasmid vectors carried by *Agrobacterium tumefaciens* (a soil bacterium). The plasmid vector is disarmed since it lacks the genes that encode the tumorigenic functions of *A. tumefaciens*. The *A. tumefaciens* mediated transformation system is a frequently employed plant transformation method used routinely in many laboratories in Australia and overseas for introducing new genes into plants without causing any biosafety problems.

Consultation on preparation of the Risk Assessment and Risk Management Plan

The Regulator has made an initial assessment as to whether the proposed release may pose significant risks to human health and safety or the environment, in accordance with section 49 of the Act. Due to the low risk potential of the GMOs, the control measures that will be imposed, and the limited scale and scope of the dealings, **the Regulator has decided that the proposed release does not pose a significant risk to human health and safety or the environment.**

This means that the Regulator is **not required to seek public comment** on the assessment of this proposal until after a risk assessment and risk management plan (RARMP) has been prepared for consultation. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 060/2005.

In preparing the RARMP, the Regulator will seek input from a wide range of key stakeholders and expert groups including State and Territory Governments, Australian Government agencies, the Minister for the Environment and Heritage, the Gene Technology Technical

Advisory Committee and relevant local councils. The Regulator will consult again with these prescribed agencies and authorities, as well as the public, in finalising the RARMP, which then forms 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 an extended **six** week consultation period in **November 2005**. 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. Summaries and copies of the RARMP will be available from the OGTR, or on the OGTR website.

If you have any questions about the application or the assessment process, please contact the OGTR at:

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