



Office of the Gene Technology Regulator

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 030/2002

SUMMARY INFORMATION DECEMBER 2002

Project Title:	Ongoing commercial release of colour modified carnations (Extension of deemed licence GR-2)
Applicant:	Florigene
Common name of the parent organism:	Carnation
Scientific name of the parent organism:	<i>Dianthus caryophyllus</i>
Modified trait(s):	Modified flower colour
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none"> • A gene coding for dihydroflavonol reductase (DFR) • A gene coding for flavonoid 3', 5' hydroxylase (F3'5'H) • A selectable marker gene (SuRB) whose protein confers resistance to sulphonylurea herbicides
Proposed Location	<ul style="list-style-type: none"> • Research and stock plants: held at Florigene • Release of cuttings: a single propagator in Victoria • Release of rooted cuttings: between 3 and 6 growers in Australia (Victoria, South Australia, Queensland, Western Australia) • Release of cut flowers: Australia wide* • Release of flowering plants: Australia wide* <p style="margin-top: 10px;">*NB Exporting plants to Tasmania also requires approval from the Tasmanian State Government under the <i>Plant Quarantine Act 1997</i> (Tasmania).</p>
Proposed Release Size:	The release area covers the propagation, growth and distribution of both GM plants and cut flowers Australia-wide
Proposed Time of Release:	June 2003*
	* This is an extension of the ongoing commercial release of GR-2 issued in 1995.

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), a Commonwealth 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 issuing a licence.

The application and the proposed dealings

The OGTR has received an application from Florigene for a licence for the ongoing commercial release of genetically modified carnations (*Dianthus caryophyllus*) that have been modified for flower colour. The current application is an extension of a general release (GR-2) that was approved on 25 September 1995 under the former voluntary system (GMAC).

The Act includes transitional arrangements for dealings previously approved by GMAC. Section 190 of the Act provides for those dealings for which an advice to proceed had been issued by GMAC prior to the commencement of the Act on 21 June 2001 to be 'deemed' to be licensed for the purposes of the Act. The transitional period stipulated by the Act is two years. The Act therefore requires that dealings covered by 'deemed' licences that are proposed to continue beyond the two year transition period, ie 21 June 2003, require assessment and licensing. The dealings authorised by GMAC under GR-2 are proposed to be continued beyond 21 June 2003.

The present application is for a licence to deal with **any** transgenic carnation line produced after transformation with either of two binary vectors, pCGP1470 or pCGP1991. Florigene has indicated that in the medium term its intention is to seek approval for the products described under the dealings to be placed on the GMO Register.

Previous releases of the GMO

Under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC), Florigene carried out nine releases of GM carnations. Seven of these were planned releases (PR-19, PR-19X, PR-28, PR-29, PR-28X, PR-29X, PR-84), and two were general releases (GR-1, 2). Presently, Florigene is the only company in the world dealing in genetically modified carnations.

Previous releases of GM carnation are:

- PR-19 (1992-1995): Planned release of GM carnation to prolong vase life of flowers for trialing under commercial glasshouse production conditions.
- PR-19X (1993-1995): The above trial was extended to include five different GMOs designed to prolong vase life of flowers.
- PR-28 (1994-1995): Planned release of GM carnation containing genes to modify flower colour to produce mauve/purple/violet flowers under a semi-contained field trial.
- PR-29 (1994-1996): Planned release of GM carnation modified for enhanced vase life.
- PR-28/29X (1994-1997): Extension to PR-28 and PR-29 for inclusion of an igloo trialing area.
- PR-84 (1997-1999): Planned release of GM carnation modified for resistance to fungal pathogens.
- GR-1 (1995-2003): General release for the commercialisation of GM carnation for improved vase life.
- GR-2 (1995-2003): General release for the commercialisation of violet carnation developed using genetic engineering.

There have been no reports of adverse effects on human health or the environment resulting from these releases. Note that GM carnations have been commercially available in Australia since 1996.

Parent organism

The parent organism is carnation, *Dianthus caryophyllus*. *D. caryophyllus* belongs to the Caryophyllaceae family, a temperate northern hemisphere family containing around 2100 species in 89 genera. The *Dianthus* genus contains approximately 300 species and is native to Europe, Asia, North Africa, and the Arctic region where one species is found. Carnation is exotic to Australia but has been grown commercially as a flower crop since 1954. At present the industry produces approximately 140 million cut flowers per annum across a total of 100 ha in Victoria, South Australia, Western Australia, and New South Wales. Victoria is the largest production centre.

Genetic modification and its effect

The carnations have been genetically modified to produce violet, mauve, or purple coloured flowers. Colour in flowers is attributed to the presence of two pigment types - flavonoids and carotenoids. The carotenoids are responsible for yellow through orange colours however most plants do not contain carotenoid pigments. Many flavonoids are flower pigments such as the anthocyanins (water soluble plant pigments). There are three groups of anthocyanins, the delphinidins that produce blue flower colour, cyanidins that produce red or pink flower colour, and pelargonidins that produce orange or brick red flower colour. Non-genetically modified carnations lack the part of the anthocyanin biosynthetic pathway that is responsible for the production of delphinidins. This includes the enzyme flavonoid 3', 5' hydroxylase (F3'5'H) that converts either dihydrokaempferol (DHK) or dihydroquercetin (DHQ) to dihydromyricetin (DHM), and the dihydroflavonol reductase (DFR) enzyme that converts DHM to delphinidin-3-glycoside. The GM carnations in this application contain the genes coding for the enzymes F3'5'H and DFR, a selectable marker conferring resistance to

sulfonylurea herbicides, and regulatory sequences designed to enhance expression of the inserted genes (see Tables 1 and 2 below).

Table 1 – gene construct of binary vector pCGP1470

Promoter	origin	Gene	origin	Terminator	origin
35S	CaMV (cauliflower mosaic virus)	SuRB	<i>N. tabacum</i> (tobacco)	SuRB	<i>N. tabacum</i> (tobacco)
CHS	<i>A. majus</i> (snap dragon)	F3'5'H	<i>Petunia</i>	D8	<i>Petunia</i>
MAC-1	CaMV <i>A. tumefaciens</i> (crown gall)	DFR	<i>Petunia</i>	<i>mas</i>	<i>A. tumefaciens</i> (crown gall)

Table 2 – gene construct of binary vector pCGP1991

Promoter	origin	Gene	origin	Terminator	origin
35S	CaMV	SuRB	<i>N. tabacum</i> (tobacco)	SuRB	<i>N. tabacum</i> (tobacco)
CHS	<i>A. majus</i> (snap dragon)	F3'5'H	<i>Viola</i> (pansy)	D8	<i>Petunia</i>
DFR 5'	<i>Petunia</i>	DFR	<i>Petunia</i>	DFR	<i>Petunia</i>

Some of the regulatory sequences are derived from plant pathogens (Cauliflower Mosaic Virus – CaMV, and Crown Gall – *Agrobacterium tumefaciens*). However, they represent only a very small proportion of the pathogen genome and the sequences are not, in themselves, infectious or pathogenic.

Method of gene transfer

Two binary vectors have been constructed to contain the DFR, F3'5'H, and SuRB genes as well as associated regulatory sequences. Transgenic carnations have been produced by *Agrobacterium tumefaciens*-mediated transformation using the disarmed strain AGL0. The *Agrobacterium*-mediated DNA transformation system is well understood and used extensively in genetic transformation of plants. The entire DNA sequence of the transgenes and the vectors used to transform the plants are known.

Consultation on draft 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 or the environment, in accordance with section 49 of the Act. Due to the low risk potential of the GMO and the limited scale of the proposed field trial, **the Regulator has decided that the proposed release does not pose a significant risk to human health or the environment.**

This means that the Regulator is **not required to seek public comment** on the assessment of this proposal until the risk assessment and risk management plan has been prepared. At this stage, the plan is expected to be issued by the **early 2003**. In the interim, copies of the

application are available on request from the OGTR. Please quote application number DIR 030/2002.

As required by section 50 of the Act, in preparing the risk assessment and risk management plan in relation to the licence application, the Regulator will seek input from a wide range of key stakeholders and expert groups comprising State and Territory Governments, relevant Commonwealth agencies, the Environment Minister, the Gene Technology Technical Advisory Committee and appropriate local councils. As required by section 52 of the Act, the Regulator will again consult with these prescribed agencies and authorities in finalising the plan.

The public will also be invited to provide comment on the risk assessment and risk management plan over a seven week consultation period, via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. Summaries and copies of the risk assessment and risk management plan 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 Office of the Gene Technology Regulator
MDP 54, PO Box 100, WODEN ACT 2606**

Telephone: 1800 181 030

Fax: 02 6271 4202

Email: ogtr@health.gov.au

Website: www.ogtr.gov.au