



APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 068/2006

SUMMARY INFORMATION

Project Title:	Limited and controlled release of genetically modified torenia with altered flower colour¹
Applicant:	Florigene Pty Ltd
Common name of the parent organism:	Torenia
Scientific name of the parent organism:	<i>Torenia x hybrida</i>
Modified trait(s):	Altered flower colour
Identity of the gene(s) responsible for the modified trait(s):	Partial gene sequences for altered flower colour: <ul style="list-style-type: none">• <i>ans</i> (anthocyanidin synthase)• <i>f3'5'h</i> (flavonoid 3',5' hydroxylase)• <i>f3'h</i> (flavonoid 3'-hydroxylase)• <i>f3h</i> (flavanone 3β-hydroxylase) all partial sequences derived from <i>Torenia</i> Complete gene sequences for altered flower colour: <ul style="list-style-type: none">• <i>dfr</i> (dihydroflavonol-4-reductase) derived from <i>Pelargonium</i>• <i>as</i> (aureusidin synthase) derived from <i>Antirrhinum</i>• <i>4'cgt</i> (chalcone-4'-O-glucosyltransferase) derived from <i>Antirrhinum</i> Selectable marker: <ul style="list-style-type: none">• <i>nptII</i> (neomycin phosphotransferase type II) derived from <i>Escherichia coli</i>
Proposed Location(s):	One site in the City of Darebin, Victoria
Proposed Release Size:	Up to 200 plants in an area not exceeding 100m ²
Proposed Time of Release	October 2007 – May 2008

¹The title of the licence application submitted by Florigene was '*Outdoor trial of colour modified Torenia spp.*'.

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 licence².

The application and the proposed dealings

The OGTR has received an application from Florigene Pty Ltd (Florigene) for a licence for the intentional release of up to nine genetically modified (GM) torenia (*Torenia x hybrida*) lines into the environment on a limited scale and under controlled conditions.

The GM torenia lines were originally developed in Japan and imported by Florigene under an Australian Quarantine Inspection Service import permit. They contain up to three partial or complete gene sequences which affect the production of different coloured pigments (anthocyanins) in flowers.

The proposed field trial would involve growing up to 200 plants in hanging baskets suspended over gravel or concrete in an area not exceeding 100m² in the City of Darebin, Victoria, from October 2007 to May 2008.

The aim of the proposed release is to assess the performance of the GM torenia lines under conditions comparable to normal cultivation. The expression of the introduced genes, horticultural characteristics such as plant size, number and longevity of flowers, flower colour stability and susceptibility to pests and diseases would be evaluated. Torenias are used as ornamental plants and none of the GM plant materials from the proposed release would be used in human food, animal feed or in the manufacture of plant products.

The applicant has proposed a number of containment measures for the conduct of the field trial that will be considered during the assessment of the application including:

- monitoring the area below the hanging baskets during and after the trial for viable GM torenia plant materials, such as detached stem pieces or prunings, and destroying any found
- enclosing the release area within 2.1m fencing with a lockable gate
- destruction of GM plant materials not required for further research or propagation by procedures approved by the OGTR
- sterilising the soil used to grow the GM torenia plants
- transportation of GM plant materials in accordance with OGTR transportation guidelines

Previous releases of the GMOs

There have been no previous releases of the GM torenia lines in Australia. However, roses and carnations genetically modified for altered flower colour using the same or similar genes have previously been approved for releases. GM roses were recently approved for a limited and controlled release in an insect-proof greenhouse under licence DIR060/2005 and GM carnations were approved for unrestricted commercial release under licence DIR030/2002.

Parent organism

The parent organism, torenia (*Torenia x hybrida*), is derived from an inter-specific cross between two exotic species, *T. fournieri* Lind. and *T. concolor* Lind. The inter-specific hybrid is sterile and, thus,

² More information on the comprehensive assessment required for licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (OGTR) (Free call 1800 181 030) or at <<http://www.ogtr.gov.au/ir/process.htm>>. Further information on the evaluation process is contained in the Regulator's *Risk Analysis Framework* (OGTR, 2005), <<http://www.ogtr.gov.au/pdf/rafinal2.2pdf>>.

does not set seed. Propagation is by cuttings or tissue culture. Torenia are characterised by profuse, long term flowering, and a fast growing, spreading habit which is suitable for both landscaping and hanging baskets (where they are generally treated as annuals). A number of non-GM torenia cultivars are available commercially in Australia. Two cultivars that were bred as pot plants, 'Summerwave® blue' and 'Summerwave® violet', were genetically modified to generate the GM torenia lines proposed for release.

Genetic modification and its effect

The principle class of pigments responsible for flower colour are anthocyanins. The partial or complete gene sequences introduced into the nine GM torenia lines proposed for release are designed to alter the production of different anthocyanins and, therefore, alter flower colour.

The partial gene sequences were derived from torenia and are designed to suppress the function of endogenous genes responsible for flower colour. The complete gene sequences were derived from snapdragon (*Antirrhinum majus*) or geranium (*Pelargonium x hortorum*) and their introduction will increase production of other colour pigments. In greenhouse conditions, the introduction of partial or complete gene sequences into the GM torenia lines produced a range of flower colours including white, pink, yellow, purple, blue and violet.

The GM torenia lines also contain a commonly used selectable marker gene, *nptII* (neomycin phosphotransferase type II), from the gut bacterium *Escherichia coli* that confers resistance to the antibiotics neomycin and kanamycin. The marker gene enabled the identification and selection of genetically modified plant tissues during the initial laboratory stage of development of the GMOs.

Short regulatory sequences that control expression of the introduced genes are also present in all the GM torenia lines. They are either derived from cauliflower mosaic virus (CaMV) or a common soil bacterium, *Agrobacterium tumefaciens*. Although CaMV and *A. tumefaciens* are plant pathogens, the regulatory sequences comprise only a small part of their total respective genome, and are not capable of causing diseases.

Method of genetic modification

The GM torenia lines were produced by introducing gene constructs designed to alter flower colour, along with regulatory sequences, into the parent torenia cultivars 'Summerwave® blue' and 'Summerwave® violet', on plasmid vectors carried by *A. tumefaciens*. These vectors are 'disarmed' since they lack the genes that encode the tumour-inducing functions of *A. tumefaciens*.

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. Based on the characteristics of the GM torenia lines, the introduced genes, 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 068/2006.

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 the relevant local council. 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 a six week consultation period in **mid-October 2006**. 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 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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