



Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

20 December 2006

**TECHNICAL SUMMARY OF THE
RISK ASSESSMENT AND RISK MANAGEMENT PLAN**
for
APPLICATION NO. DIR 068/2006
from
FLORIGENE PTY LTD

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence (DIR 068/2006) to Florigene Pty Ltd (Florigene) for dealings involving the intentional release (DIR) of genetically modified (GM) torenia lines into the Australian environment on a limited scale and under controlled conditions.

The DIR 068/2006 licence permits the release of nine GM torenia lines under limited and controlled conditions.

The *Gene Technology Act 2000* (the Act), the *Gene Technology Regulations 2001* (the Regulations) and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision whether or not to issue a licence to deal with a GMO.

The Regulator's *Risk Analysis Framework* explains the approach used to evaluate licence applications and to develop the Risk Assessment and Risk Management Plans (RARMPs) that form the basis of her decisions¹.

This RARMP for DIR 068/2006 has been finalised in accordance with the gene technology legislation. Matters raised in the consultation process regarding risks to the health and safety of people or the environment from the proposed dealings were taken into account by the Regulator in deciding to issue a licence and the licence conditions that have been imposed.

¹ More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>>.

Application

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| Title: | Limited and controlled release of genetically modified torenia with altered flower colour ² |
| Applicant: | Florigene Pty Ltd |
| Common name of the parent organism: | Torenia |
| Scientific name of the parent organism: | <i>Torenia X hybrida</i> |
| Modified traits: | Altered flower colour |
| Identity of the genes responsible for the modified traits: | <p>Partial gene sequences for altered flower colour:</p> <ul style="list-style-type: none"> • <i>ans</i> (anthocyanidin synthase) from <i>Torenia X hybrida</i> • <i>f3'5'h</i> (flavonoid 3', 5' hydroxylase) from <i>Torenia X hybrida</i> • <i>f3'h</i> (flavonoid 3'-hydroxylase) from <i>Torenia X hybrida</i> • <i>f3h</i> (flavanone 3β-hydroxylase) from <i>Torenia X hybrida</i> <p>Complete gene sequences for altered flower colour:</p> <ul style="list-style-type: none"> • <i>dfr</i> (dihydroflavonol-4-reductase) from <i>Pelargonium X hortorum</i> • <i>as</i> [aureusidin (aurone) synthase] from <i>Antirrhinum majus</i> • <i>4cgt</i> (chalcone-4'-O-glucosyltransferase) from <i>Antirrhinum majus</i> <p>Selectable marker:</p> <ul style="list-style-type: none"> • <i>nptII</i> (neomycin phosphotransferase type II) from <i>Escherichia coli</i> |
| Proposed location: | One site in the City of Darebin, Victoria |
| Trial size: | Up to 200 GM plants in an area not exceeding 100 m ² |
| Proposed time of the trial: | October 2007 – May 2008 |

Florigene applied for a licence for the limited and controlled release of nine torenia (*Torenia X hybrida*) lines that have been genetically modified (GM) to produce a range of flower colours. A field trial with up to 200 GM plants is proposed at one site not exceeding 100 m² in the City of Darebin, Victoria, from October 2007 to May 2008. The purpose of the trial is to evaluate their outdoor performance by measuring horticultural characteristics such as plant size, leaf size, number and longevity of flowers, flower colour stability, anther number, pollen viability, and susceptibility to pests and diseases compared to the non-GM parent plant. No products from the release will be used as human food, animal feed or in the manufacture of plant products.

The nine GM torenia lines release have been vegetatively propagated for seven generations in contained glasshouses by Florigene. The parent organism (*Torenia X hybrida*) is derived from an inter-specific cross between two exotic species, *Torenia fournieri* Lind. and *Torenia concolor* Lind. The applicant states that the inter-specific hybrid is sterile and does not set seed or produce viable pollen. There are two non-GM cultivars of *T. X hybrida* currently available commercially in Australia, Summerwave® blue and Summerwave® violet.

The principle class of pigments responsible for flower colour are anthocyanins. The partial or complete gene sequences introduced into the nine GM torenia lines 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. Under glasshouse conditions, the introduction of partial or complete gene sequences into the GM torenia lines produced a range of flower colours including white, blue with white sectors, pale pink, dark pink and pale yellow.

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

² The title of the licence application submitted by Florigene was 'Outdoor trial of colour modified *Torenia* spp'

the antibiotics neomycin and kanamycin. The marker gene enabled the identification and selection of GM plant tissues during the initial laboratory stage of development of the GMOs.

The GM plants would be grown individually in hanging baskets suspended above a concrete or gravel surface and the applicant proposed a number of other measures to limit their spread and persistence in the environment. These were taken into account in establishing the risk assessment context and their suitability for limiting the release to the location, size and duration requested by the applicant was considered as part of the risk assessment process.

Risk assessment

The risk assessment considered information contained in the application, current scientific knowledge, and issues relating to risks to human health and safety and the environment raised in submissions received from consultation with a wide range of prescribed experts, agencies and authorities on the application (summarised in Appendix B of the RARMP). No issues were raised in the comments received on the consultation version of the RARMP that required further analysis or consideration (Appendix D of the RARMP).

Submissions from a member of the public on the application and the consultation RARMP and how these were taken into account in the RARMP are summarised in Appendix C and E of the RARMP, respectively.

A reference document, *The Biology and Ecology of Torenia (Torenia X hybrida) in Australia* (OGTR 2006), was produced to inform the risk assessment process for licence applications involving GM torenia plants. The document is available from the OGTR or from the website <<http://www.ogtr.gov.au>>.

A hazard (source of potential harm) may be an event, substance or organism. A risk is identified when a hazard is considered to have some chance of causing harm. Those events that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

The hazard identification process considered the circumstances by which the health and safety of people or the environment may be adversely affected by exposure to the GMOs, GM plant materials, GM plant by-products, the introduced genes, or products of the introduced genes.

Sixteen events were identified and characterised that may give rise to harm to people or the environment as a result of the trial of the nine GM torenia lines.

These sixteen events included consideration of whether, or not, expression of the introduced genes could produce proteins that are toxic to people or other organisms, allergenic, result in unintended changes in biochemistry or physiology, or alter characteristics that may impact on spread and persistence of the GMOs. In addition, consideration was given to the potential for gene flow to other organisms or unauthorised activities, and whether harm could arise from any of these events.

None of the sixteen events were considered to give rise to an identified risk that required further assessment. The principle reasons comprise:

- the widespread presence of the same or similar proteins and end-products from the introduced genes occurring naturally in the environment and lack of evidence of harm from them
- the small scale of the trial that is limited in both area and duration

- the containment and disposal measures proposed by Florigene to limit the spread of GM torenia plants and plant materials
- the prohibition to use GM plant materials in human food or animal feed or in the manufacture of plant products
- the limited opportunity and ability of the GM torenia lines to reproduce or transfer the introduced genes to other organisms because of the inherent sterility of the parent cultivar.

Therefore, the risks of harm to the health and safety of people, or the environment, from the proposed trial of the GM torenia lines were considered to be **negligible**.

Risk management

A risk management plan builds upon the risk assessment to consider whether any action is required to mitigate the identified risks, and what can be done to protect the health and safety of people and the environment.

The risk assessment process identified and characterised sixteen events whereby the trial of nine GM torenia lines might give rise to harm to people or the environment. As none of the sixteen events were considered to give rise to an identified risk that requires further assessment, the level of risk is considered to be negligible.

However, containment measures have been imposed to restrict the release to the, size, duration and location requested by the applicant, as these were important parameters in establishing the context for assessing the risks.

Licence conditions

A number of licence conditions have been imposed to limit and control the release, including requirements to:

- grow the GM torenia plants in individual pots suspended above a gravel or concrete surface
- enclose the trial site within a 2.1m fence, with lockable gates
- monitor the gravel/concrete area below the hanging pots during the trial for GM torenia plant materials such as detached stem pieces or prunings and destroy any found
- destroy GM and other plant waste material
- clean the site and sterilise the soil used to grow the GM torenia plants at the end of the trial
- transport of GM plant materials in accordance with OGTR transportation guidelines

Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework. Other agencies that also regulate GMOs or GM products include FSANZ (Food Standards Australia New Zealand), APVMA (Australian Pesticides and Veterinary Medicines Authority), Therapeutic Goods Administration (TGA), National Industrial Chemicals

Notification and Assessment Scheme (NICNAS), National Health and Medical Research Council (NHMRC) and Australian Quarantine and Inspection Service (AQIS). Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies³.

FSANZ is responsible for human food safety assessment and food labelling, including GM food. As *Torenia* spp. are ornamental plants, the applicant does not intend any material from the GM torenia lines proposed for limited and controlled release to be used in human food. Accordingly, the applicant has not applied to FSANZ for evaluation of any of the GM torenia lines for use in human food.

The GM torenia lines to be used in the proposed trial were developed in Japan and brought to Australia where they have been grown in a physical containment level 2 (PC2) glasshouses under Notifiable Low Risk Dealing (NLRD) 2023/2006 (OGTR Reference).

AQIS is responsible for monitoring imports to prevent the introduction of exotic pests, weeds and diseases into the environment. An importer is required to notify AQIS if they are importing GMOs. Additionally, as the importation of tissue cultures of the nine GM torenia lines constituted a dealing under the *Gene Technology Act 2000*, the importer required an authorisation under this Act for the import to lawfully proceed. Tissue cultures of the GM torenia lines have been imported by Florigene under AQIS permits 200319814 and 200515938 in relation to NLRD 2023/2006.

Identification of issues to be addressed for future releases

The risk assessment identified additional information that may be required to assess an application for a larger scale trial, reduced containment conditions or a commercial release of any of these GM torenia lines. This would include:

- confirmation that GM torenia lines do not produce viable pollen and seed
- confirmation that detached stem pieces do not form adventitious roots under natural conditions
- altered horticultural characteristics indicative of weediness
- susceptibility to diseases and pests compared to the parent organism
- molecular characterisation of GM torenia lines selected for possible future releases.

Conclusions of the RARMP

The risk assessment concluded that this limited and controlled release of nine GM torenia lines with altered flower colour at a single site in the City of Darebin, Victoria, poses **negligible risks** to the health and safety of people and the environment.

The risk management plan concluded that these negligible risks do not require specific risk treatment measures. However, licence conditions have been imposed to limit the release to the size, location and duration requested by the applicant.

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