



4 September 2008

**TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK  
MANAGEMENT PLAN  
FOR  
APPLICATION NO. DIR 084/2008  
FROM  
FLORIGENE PTY LTD**

### ***Introduction***

The Acting Gene Technology Regulator (the Acting Regulator) has made a decision to issue a licence (DIR 084/2008) to Florigene Pty Ltd (Florigene) for dealings involving the limited and controlled release of genetically modified (GM) torenia lines into the Australian environment.

The *Gene Technology Act 2000* (the Act), the Gene Technology Regulations 2001 and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision whether to issue a licence to deal with a GMO. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Acting Regulator in accordance with the *Risk Analysis Framework* and finalised following consultation with a wide range of experts, agencies and authorities and the public<sup>1</sup>.

### ***The application***

Florigene applied for a licence for dealings involving the intentional release of three lines<sup>2</sup> of torenia (*Torenia x hybrida*) that have been genetically modified for enhanced phosphate uptake on a limited scale and under controlled conditions. The trial is authorised to take place at one site in the local government area of Darebin, Victoria, on a maximum total area of 20 m<sup>2</sup>, between October 2008 and May 2009.

The three GM torenia lines contain the *phosphate starvation response regulator 1 (PHR1)* gene from thale cress (*Arabidopsis thaliana*) under the control of a different promoter in each

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<sup>1</sup> More information on the process for assessment of licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/process-1>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2007) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

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

line. The *PHR1* gene encodes a transcription factor<sup>3</sup> thought to play a role in plant responses to phosphate deficiency.

In addition, all of the GM torenia lines contain the antibiotic resistance gene, *neomycin phosphotransferase type II (nptII)*. This gene, encoding the enzyme neomycin phosphotransferase, was derived from *Escherichia coli*, and confers kanamycin or neomycin resistance on the GM plant. The *nptII* gene was used as a selective marker to identify transformed plants during their initial development in the laboratory.

The purpose of the trial is to conduct proof of concept research involving experiments with the GM torenia lines to assess their capacity to absorb phosphate and slow or repress algal overgrowth in the surrounding water. The GM torenia plants will not be used for human food or animal feed.

Florigene proposed a number of controls to restrict the dissemination or persistence of the GM torenia lines and their genetic material into the environment. These controls have been considered during the evaluation of the application.

### **Confidential Commercial Information**

The identity of one of the promoters used to control expression of the introduced gene in one of the three GM torenia lines has been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information was made available to the prescribed experts and agencies that were consulted on the RARMP for this application.

### **Risk assessment**

The risk assessment considered information contained in the application (including proposed containment measures), relevant previous approvals, 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 new risks to people or the environment were identified from the advice received on the consultation RARMP.

No submissions were received from the public.

A reference document on the parent organism, *The Biology of Torenia spp. (torenia)*, 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/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

The risk assessment begins with a hazard identification process to consider what harm to the health and safety of people or the environment could arise during this release of GMOs due to gene technology, and how it could happen, in comparison to the non-GM parent organism and in the context of the proposed receiving environment.

Eight events were identified whereby the proposed dealings might give rise to harm to people or the environment. This included consideration of whether, or not, expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms; alter characteristics that may impact on the spread and persistence of the GM

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<sup>3</sup> A transcription factor is any protein required for the recognition, by RNA polymerases, of specific regulatory sequences in genes (eg a promoter)

plants; or produce unintended changes in their biochemistry, physiology or ecology. The opportunity for gene flow to other organisms and its effects if this occurred was also assessed.

A **risk** is only identified when a hazard is considered to have some chance of causing harm. Events that do not lead to an adverse outcome, or could not reasonably occur, do not represent an identified risk and do not advance any further in the risk assessment process.

The characterisation of the eight events in relation to both the magnitude and probability of harm, in the context of the control measures proposed by the applicant, did not give rise to any identified risks that required further assessment. The principle reasons for this include:

- ♦ limits on the size and duration of the release proposed by Florigene
- ♦ suitability of controls proposed by Florigene to restrict the dissemination or persistence of the GM torenia plants and their genetic material
- ♦ limited capacity of the GM torenia lines to spread and persist outside the areas proposed for release
- ♦ limited ability and opportunity for the GM torenia lines to transfer the introduced genes to other torenia plants or other sexually related species
- ♦ none of the GM plant materials or products will be used in human food or animal feed
- ♦ widespread presence of the same or similar proteins encoded by, and end products produced as a result of the activity of, the introduced genes in the environment and lack of known toxicity or evidence of harm from them.

Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM torenia lines into the environment are considered to be **negligible**. Hence, the Acting Regulator considers that the dealings involved in this proposed release **do not pose a significant risk** to either people or the environment.

### ***Risk management***

The risk management process builds upon the risk assessment to determine whether measures are required in order to protect people and/or the environment. As none of the eight events characterised in the risk assessment are considered to give rise to an identified risk that requires further assessment, the level of risk is considered to be **negligible**.

The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation in the risk management plan. However, a range of measures have been imposed to limit the release to the size, location and duration requested by the applicant, as these were an important part of establishing the context for assessing the risks.

### ***Licence conditions to manage this limited and controlled release***

The Acting Regulator has imposed a number of licence conditions to limit and control the release, including requirements to:

- ♦ conduct the release on a maximum total area of 20 m<sup>2</sup> at one site in the local government area of Darebin (Victoria) between October 2008 and May 2009

- ♦ locate the trial site within the perimeter of existing Florigene greenhouse infrastructure, which is surrounded by a 2.1 metre fence and lockable gates
- ♦ grow the plants hydroponically at ground level in 1000 litre plastic tubs
- ♦ visually monitor the site twice per week during the 12-week growing period
- ♦ complete full written inspections of the site: on a monthly basis during the 12-week growing period; and after severe weather; and if any non-compliances are detected during a bi-weekly visual monitoring
- ♦ destroy all plant materials not required for laboratory analysis
- ♦ clean all equipment used in cultivation practices, and
- ♦ not permit any materials from the release to be used in human food or animal feed.

The Regulator has issued guidelines and policies for the transport, supply and storage of GMOs (*Guidelines for the transport of GMOs, July 2007*<sup>4</sup>; *Policy on transport and supply of GMOs, July 2005*<sup>5</sup>). Licence conditions based on these guidelines and policies have also been imposed to control possession, use or disposal of the GMOs for the purposes of, or in the course of, the authorised dealings.

### ***Other regulatory considerations***

Australia's gene technology regulatory system operates as part of an integrated legislative framework that avoids duplication and enhances coordinated decision making. Dealings conducted under a licence issued by the Regulator may also be subject to regulation by other agencies that also regulate GMOs or GM products including Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Quarantine and Inspection Service (AQIS)<sup>6</sup>.

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves proof of concept research, the applicant does not intend any material from the GM torenia lines proposed for release to be used in human food. Accordingly, the applicant has not applied to FSANZ to evaluate any of the GM torenia lines. However, the flowers of torenia are reportedly consumed by some people in salads and FSANZ approval would need to be obtained before they could be sold as human food in Australia.

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<sup>4</sup>Guidelines for the transport of GMOs

<<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/transport-guide-1>>

<sup>5</sup> Policy on transport and supply of GMOs

<<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/policies-1>>

<sup>6</sup> 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/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

### ***Identification of issues to be addressed for future releases***

Additional information has been identified that may be required to assess an application for a large scale or commercial release of any of these GM torenia lines that may be selected for further development, or to justify a reduction in control measures. This would include:

- ◆ characterisation of the genetic material inserted into the plants, including genetic stability
- ◆ characteristics indicative of weediness including altered sexual and asexual reproductive capacity, tolerance to environmental stresses and disease, altered plant growth in soil
- ◆ additional data on the potential toxicity and allergenicity of plant materials from the GM torenia lines.

### ***Suitability of the applicant***

The Regulator determined, at the commencement of the assessment process for this application, that Florigene is suitable to hold a DIR licence under the requirements of section 58 of the Act. The Acting Regulator is satisfied that Florigene remains suitable as no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under OGTR legislation relating to the health and safety of people or the environment, and the organisation has confirmed its ability to comply with the licence conditions.

### ***Conclusions of the RARMP***

The risk assessment concluded that this limited and controlled release of three GM torenia lines on a maximum total area of 20 m<sup>2</sup> over eight months in the Victorian local government area of Darebin poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

The risk management plan concluded that these **negligible** risks do not require specific risk treatment measures. However, licence conditions have been imposed to restrict the dissemination and persistence of the GMOs and their genetic materials in the environment and to limit the release to the size, location and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.