



**EXECUTIVE 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 for dealings involving the intentional release (DIR) of genetically modified (GM) torenia lines into the Australian environment, in respect of application DIR 068/2006 from Florigene Pty Ltd (Florigene).

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) and the Gene Technology Regulations 2001 (the Regulations) govern the process undertaken by the Regulator before a decision is made on whether or not to issue a licence. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with the *Risk Analysis Framework* and in consultation with a wide range of experts, agencies and authorities, and the public.

More information on the process required for the comprehensive assessment of 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/>.

The application

Florigene applied for a licence to trial nine GM torenia lines (*Torenia X hybrida*) at a single site in the City of Darebin, Victoria, from October 2007 to May 2008 under limited and controlled conditions. Torenia is a widely grown ornamental plant. The nine GM torenia lines contain up to three partial or complete gene sequences, which affect the production of different coloured pigments (anthocyanins) in the flowers. The gene sequences were derived either from torenia or two other common garden plants (snapdragon and geranium). The GM torenia lines also contain an antibiotic resistance marker gene from a common bacterium, which helped identify and select modified plants during their development in the laboratory.

The GM torenia lines were originally developed in Japan and seven generations have been vegetatively propagated in certified contained glasshouses.

The proposed field trial would involve growing up to 200 GM plants individually in hanging baskets suspended over gravel or concrete in an area not exceeding 100 m². The aim of the trial is to assess the outdoor performance of the nine GM torenia lines under conditions comparable to normal cultivation. 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 will be evaluated compared to the non-GM parent plant. None of the GM plant materials from the trial would be used as human food, animal feed or in the manufacture of plant products.

Florigene proposed a number of measures to limit the spread and persistence of the GMOs and the introduced genetic material, which have been considered during the evaluation of the application.

Risk assessment

The hazard identification process considered the circumstances by which people or the environment may be exposed to the GMOs, GM plant materials, GM plant by-products, the introduced genes, or products of the introduced genes.

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.

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, and 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 the 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

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 16 events identified and characterised in the risk assessment were considered to give rise to an identified risk that requires further assessment, the level of risk was 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. However, containment and disposal measures have been imposed to restrict the release to the location, size and duration to those requested by the applicant, as these were an important part of establishing the context for assessing the risks.

The licence conditions require the applicant to limit the duration of the trial to eight months at a single site; restrict access to the site; implement measures to limit the spread and persistence of the GMOs; prevent the use of the GMOs, or materials from the GMOs, for any other purposes than research and clean the site to ensure all GMOs are destroyed¹.

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 contain the release to the location, size and duration requested by the applicant.

¹ The licence for DIR 068/2006 is available on the OGTR website (<<http://www.ogtr.gov.au/gmorec/ir.htm#table>> via the link to DIR 068/2006).