



4 September 2008

**EXECUTIVE 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 for dealings involving the limited and controlled release of three lines of torenia genetically modified for enhanced phosphate uptake into the environment in respect of application DIR 084/2008 from Florigene Pty Ltd (Florigene).

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 genetically modified (GM) torenia lines on a limited scale and under controlled conditions. The GM torenia lines have been modified to enhance their capacity to absorb phosphate. The release would involve growing a maximum of 400 plants hydroponically 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 GM torenia lines also contain an antibiotic resistance selectable marker gene, which was used to identify transformed plants during their initial development in the laboratory.

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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>>.

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.

Florigene proposed a number of controls to restrict the dissemination or persistence of the GM torenia lines and the introduced genetic materials 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 Risk Assessment and Risk Management Plan (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 advice received from a wide range of experts, agencies and authorities consulted on the RARMP. No submissions were received from the public.

A **hazard** identification process was used to determine potential pathways that might lead to harm to people or the environment as a result of gene technology.

Eight events were considered 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 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 advance 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.

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 limited and controlled 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 from the proposed dealings 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 restrict the dissemination and persistence of the GMOs and their genetic material in the environment and 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.

The licence conditions require Florigene to **limit** the duration of the release to between October 2008 to May 2009 on a maximum total area of 20 m<sup>2</sup> at one site. The **control** measures to restrict the spread and persistence of the GMOs include preventing the use of GM plant materials in human food or animal feed; destroying waste GM plant materials; and transporting GM plant materials in accordance with OGTR transportation guidelines<sup>2</sup>.

### ***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.

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<sup>2</sup> The licence for DIR 084/2008 is available on the OGTR website via the link to DIR 084/2008 (<<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir084-2008>>)