



24 March 2006

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT  
AND RISK MANAGEMENT PLAN**  
for  
**APPLICATION NO. DIR 060/2005**  
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) rose lines into the Australian environment, in respect of application DIR 060/2005 from Florigene Pty Ltd (Florigene).

The DIR 060/2005 licence permits the release of three GM rose 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 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/ir/process.htm>>.

## **THE APPLICATION**

Florigene applied for a licence to release three GM rose (*Rosa X hybrida*) lines on two sites over two years (March 2006 - April 2008) in the Shire of Yarra Ranges, Victoria. The first site is an enclosed, insect-proof greenhouse where the GM rose lines will be grown hydroponically. The total size of the greenhouse is 100m<sup>2</sup>. The second site of approximately 25m<sup>2</sup> is nearby and will be used for shredding and composting of GM plant materials.

Three GM rose lines, originally developed in Japan, are proposed for release. They are hybrid tea and floribunda rose varieties which have been genetically modified by the insertion of genes that affect the production of blue coloured anthocyanin pigments (ie delphinidins), leading to light purple or violet coloured flowers.

Roses do not naturally generate the blue group of pigments, as they lack a key enzyme required for their production. The new genes were derived from other plants including black pansy, torenia, and iris. The GM rose plants also contain an antibiotic resistance marker gene from a common bacterium, which helped identify and select modified plants during their development in the laboratory.

About 100 plants of each GM rose line are proposed for release, along with 100 plants each of the two non-GM parental rose lines and 10 plants each of two other non-GM rose varieties. The purpose of the release is to propagate the three imported GM rose lines; evaluate the performance including the productivity, morphology and viability of the GM rose lines; biochemical analysis of flowers; and generate data to support a possible future application for a larger scale release.

## **RISK ASSESSMENT**

The risk assessment first considered what harm to the health and safety of people or the environment could arise as a result of gene technology, and how it could happen, during the proposed release of the GM rose lines into the environment (**hazard identification** refer to Chapter 2 of the RARMP for more information).

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 (eg soil used in the greenhouse, compost, cut flowers), the introduced genes, or products of the introduced genes.

A hazard (source of potential harm) may be an event, substance or organism (*Risk Analysis Framework*, OGTR 2005). 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 proposed release of the three GM rose 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 these events.

None of the sixteen events are considered to give rise to an identified risk that requires further assessment. The principle reasons include:

- small scale of the trial that is limited in both area and duration;
- containment and disposal measures proposed by the applicant to limit the spread of GM plant materials;
- none of the GM plant materials will be used in food or animal feed;
- the lack of toxicity or allergenicity of enzymes and end-products from the introduced genes;
- widespread presence of the same or similar genes in the environment and lack of evidence of harm from these genes;
- limited capacity of the GM rose lines to spread and persist except by intentional horticultural techniques;

- limited opportunity and ability of the GM rose lines to transfer the introduced genes to other organisms; and
- limited morphological differences between the GM rose lines compared with the parent rose lines.

Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM rose lines into the environment are considered to be **negligible**.

## **RISK MANAGEMENT**

The risk assessment process identified and characterised sixteen events whereby the proposed release of three GM rose lines might give rise to harm to people or the environment. As none of the sixteen events are considered to give rise to an identified risk that requires further assessment, the level of risk is considered to be **negligible**.

The *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 in location, size and duration to those requested by the applicant, as these were an important part of the context for assessing the risks.

The licence conditions, detailed in Chapter 4 of the RARMP, require the applicant to limit the duration of the release to two years at the two sites; prevent use of the GMOs, or materials from the GMOs, in food and animal feed; harvest flower buds (partly open); destroy GM plant materials by incineration or shredding and composting; and conduct monitoring of the disposal site to ensure all GMOs are destroyed.

## **CONCLUSIONS OF THE RARMP**

The risk assessment concludes that this limited and controlled release of three GM rose lines into the Shire of Yarra Ranges, Victoria poses **negligible** risks to the health and safety of people and the environment.

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