



19 June 2009

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND  
RISK MANAGEMENT PLAN  
FOR  
APPLICATION NO. DIR 090  
FROM  
FLORIGENE**

***Introduction***

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional, commercial scale release of a rose line genetically modified (GM) for altered flower colour in respect of application DIR 090 from Florigene Pty Ltd.

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 to issue a licence to deal with a genetically modified organism (GMO). 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 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 one line<sup>2</sup> of GM Hybrid Tea rose without specific containment measures. The GM rose line contains two genes that have been shown to alter flower colour from pink to purple/blue. In addition, the line contains an antibiotic resistance selectable marker gene, which was used to identify transformed plants during their initial development in the laboratory.

The GM rose line for commercial release is one of three lines that were approved for a limited and controlled release (see DIR 060/2005) under the current regulatory system. There have been no reports of adverse effects on human health and safety or the environment resulting from this release.

The purpose of the release is the ongoing commercial propagation of parent plants and the growing of plants for cut-flowers. Florigene intends to grow GM rose plants and handle their products (ie cut-flowers) in the same manner as non-GM rose plants. Parent plants and plants for cut-flowers will be grown by one or more growers

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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 (OGTR) (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.

registered with Florigene. Flowers that are produced will be sold through normal commercial distribution channels to the public, Australia-wide.

### ***Risk assessment***

The risk assessment took into account information contained in the application, relevant previous approvals, current scientific knowledge, and advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the application and RARMP. In taking into account a potential risk, the Regulator must consider the probability or impact of an adverse outcome over the foreseeable future.

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.

Seven 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 seven events in relation to both the magnitude and probability of harm 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 commercial release of the GM rose line into the environment are considered to be **negligible**. Hence, the Regulator considers that the dealings involved in this proposed commercial 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 seven events characterised in the risk assessment are considered to give rise to an identified risk, either in the short term or the long term, 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. Nonetheless, as part of the Regulator's oversight of licensed dealings involving the release of genetically modified organisms, the licence contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements which include an obligation to report any unintended effects.

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

The risk assessment concludes that this commercial release of one GM rose line, Australia-wide, poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

The risk management plan concludes that these negligible risks do not require specific risk treatment measures. However, general conditions have been imposed to ensure that there is safe oversight of the ongoing release.