



19 June 2009

**TECHNICAL 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 public¹.

The application

Florigene applied for a licence for dealings involving the intentional release of one line² of GM Hybrid Tea rose (*Rosa x hybrida*) into the Australian environment.

The GM rose line contains two genes that have been shown to alter flower colour from pink to purple/blue: the *Flavonoid 3'5'-hydroxylase (F3'5'H)* gene from *Viola x wittrockiana* and the *Anthocyanin 5-acyltransferase (5AT)* gene from *Torenia x hybrida*. In addition, the line contains an antibiotic resistance gene (*nptII*), which provides resistance to the antibiotic kanamycin and was used for the selection of transformed plants in the laboratory.

The GM rose line approved 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.

¹ 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>.

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

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 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 considered information contained in the application, relevant previous approvals, current scientific knowledge, and advice received from a wide range of experts, agencies and authorities on the application (summarised in Appendix B) and on the consultation RARMP (see Appendix C). No new risks to people or the environment were identified from the advice received on the consultation RARMP.

Similarly, advice received from the public on the consultation RARMP, and how it was considered is summarised in Appendix D. One public submission was received.

A reference document on the parent organism, *The Biology of Hybrid Tea Rose* (*Rosa x hybrida*) was produced to inform the risk assessment process for licence applications involving GM rose plants. The document is available from the OGTR or from the website <<http://www.ogtr.gov.au>>.

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.

In taking into account a potential risk, the Regulator must consider the probability or impact of an adverse outcome over the foreseeable future.

Seven 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 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 seven events in relation to both the magnitude and probability of harm did not give rise to any identified risks that required further assessment. The principal reasons for this include:

- the proteins encoded by the introduced genes are widespread in the environment and unlikely to be toxic/allergenic to people or toxic to other organisms
- the levels of delphinidin and myricetin end products in the GM rose line are within the ranges found normally in non-GM plants

- the genetic modifications are not expected to affect the survival or low weediness potential of the GM lines
- the low fertility of the non-GM rose parent organism is not expected to be altered by the introduced genes
- a range of morphological and physiological characteristics have been compared in the GM line and the non-GM parent and no differences have been detected apart from flower colour
- plants of the GM rose line have now been grown for several years without any unintended changes being detected.

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.

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)³.

FSANZ is responsible for human food safety assessment, including GM food. It is not intended that any material from the GM rose lines be sold for human food. Accordingly the applicant has not applied to FSANZ for evaluation of the GM rose

³ 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>>.

line for use in human food. FSANZ approval would need to be obtained before any products from the GM rose line could be sold for food.

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.