



## Office of the Gene Technology Regulator

### EXECUTIVE SUMMARY

of

### THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN

for

### APPLICATION DIR 030/2002

*(Commercial release of colour modified carnation – replacement of deemed licence GR-2)*

#### INTRODUCTION

The *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) set out requirements which the Gene Technology Regulator (the Regulator) must follow when considering an application for a licence to intentionally release a genetically modified organism (GMO) into the environment.

Section 51 of the Act requires the Regulator to prepare a risk assessment and a risk management plan (RARMP) for each licence application, in consultation with a wide range of expert groups and stakeholders, that addresses any risks to human health and safety and the environment posed by the dealings and considers how they can be managed.

#### THE APPLICATION

Florigene has applied for a licence for the continued commercial release of four lines of genetically modified carnation (*Dianthus caryophyllus*) that have been modified for flower colour. The current application (application number DIR030/2002) seeks to continue the dealings authorised by a general release approval (GR-2) issued on 25 September 1995 under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC). Section 190 of the Act includes arrangements for such dealings to be licenced for the duration of the transition period, which is stipulated as two years from the commencement of the Act on 21 June 2001. The Act requires that any dealings covered by 'deemed' licences that are proposed to continue beyond the two-year transition period, i.e. 21 June 2003, must be assessed and licensed under the provisions of the new regulatory system.

The present application is for a licence to deal with four GM lines (transformation events 123.2.38, 123.2.2, 11363, and 123.8.8) that have been produced after transformation with either of two binary vectors, pCGP1470 or pCGP1991. The release covers the propagation, growth, and distribution of both GM plants and cut flowers Australia-wide.

The GM carnation lines in this application contain two introduced genes in the anthocyanin biosynthetic pathway, DFR (dihydroflavonol 4-reductase) and F3'5'H (flavonoid 3', 5' hydroxylase), which are responsible for the production of purple, mauve, or blue flower colour. Each line also contains the selectable marker, SuRB (sulfonyleurea resistance gene B), that confers tolerance to sulfonyleurea herbicides and a range of other acetolactate synthase

(ALS) inhibiting herbicides. It is intended that the GM carnation be used solely as ornamental plants.

Since 1992 there have been a number of field trials of colour modified carnation that were conducted under the former voluntary system, as well as the continued commercial release authorised in 1995. Florigene also conducted field trials of carnations modified for increased vase life between 1992 and 1995 and a commercial release was authorised in 1995 under the former voluntary system. The deemed licence for the latter release will lapse on 21 June 2003. There have been no reports of adverse effects on human health or the environment resulting from any of these releases.

## THE EVALUATION PROCESS

A risk assessment and risk management plan was prepared in response to the application from Florigene in accordance with the Act and the Regulations, using a Risk Analysis Framework (available at [www.ogtr.gov.au/pdf/public/raffinal.pdf](http://www.ogtr.gov.au/pdf/public/raffinal.pdf)). This framework was developed by the Regulator in consultation with the public, key State, Territory and Commonwealth government stakeholders, and the Gene Technology Technical Advisory Committee. Details of the process that the Regulator must follow and of the matters that the Regulator must consider in preparing a risk assessment and a risk management plan are set out in Appendix 7 of the RARMP. The complete RARMP can be obtained from the OGTR (freecall 1800 181 030) or from the OGTR web site at [www.ogtr.gov.au](http://www.ogtr.gov.au).

Through the risk assessment process, a number of potential hazards that may be posed by the release of genetically modified carnation were evaluated on the basis of the likelihood of each hazard occurring and the likely impact of the hazard were it to be realised.

The potential hazards to human health and safety and the environment that were considered relate to:

- **Toxicity and allergenicity for humans:** GM carnation might be harmful to humans because it may be more toxic or allergenic than non-GM carnation as a result of the novel gene products or because of unforeseen or unintended effects.
- **Toxicity and for other organisms:** GM carnation might be harmful to other organisms because it may be more toxic than non-GM carnation as a result of the novel gene products or because of unforeseen or unintended effects of the modification.
- **Weediness:** GM carnation might be harmful to the environment because of an increased potential for weediness compared to conventional carnation.
- **Transfer of introduced genes to other organisms:** the new genes introduced into carnation might transfer to non-GM carnation, naturalised *Dianthus*, or to other plants or organisms, and this may have adverse consequences for the environment.

## CONCLUSIONS OF THE RISK ASSESSMENT

In summary, the Regulator considers that the hazards posed by this commercial release of carnation modified to produce purple, blue or mauve flowers are unlikely to present any risks to the health and safety of people or the Australian environment that are different to

conventional carnation. The assessment of each potential hazard identified above is summarised under a separate heading below.

### **Toxicity or allergenicity to humans**

GM carnation is unlikely to prove more toxic or allergenic to humans or other organisms than conventional carnation because:

- there have been no reports of adverse effects to human health and safety as a result of the current commercial release of carnation, which was approved in 1995;
- carnations are used for ornamental purposes only;
- concentrations of delphinidin in GM carnation are similar to a range of delphinidin producing plants including those commonly eaten by humans without adverse consequences, and toxicity studies of delphinidins and other anthocyanins using mammalian models indicate very low levels of toxicity;
- no differences were found in the biochemical profiles of GM and conventional carnation as revealed by chromatography studies;
- proteins related to the introduced proteins are common in edible plants;
- pollen is produced in very low quantities and is not aeroallergenic; and
- no homology of the novel proteins with sequences from known toxins or allergens was found.

### **Toxicity to other organisms**

GM carnation is unlikely to prove more toxic to other organisms than conventional carnation because:

- concentrations of delphinidin in GM carnation are similar to a range of delphinidin producing plants, and toxicity studies of delphinidins and anthocyanins using mammalian models indicate very low levels of toxicity;
- no differences were found in the biochemical profiles of GM and conventional carnation as revealed by chromatography studies of phenolic acids and volatile gases;
- proteins related to the introduced proteins are common in edible plants;
- no reports of adverse toxicity have been found;
- no toxic effects of GM carnation were found on the germination and growth of a number of plants; and
- no differences were found in the quantities of bacteria and fungal spores in soil taken from around GM and conventional carnation.

### **Weediness**

The risk of GM carnation establishing as a weed is negligible, and not likely to be greater than that of conventional carnation because:

- GM carnation does not share any life history characters with weedy species and the introduced proteins will not change these characters;
- the presence of the SuRB gene will only confer a selective advantage in those environments where weeds are controlled by ALS inhibiting herbicides. These

herbicides are not used in the carnation industry and carnations exist exclusively as a managed cultigen;

- GM carnation has an extremely low potential for dispersal by natural means as it does not set seed;
- GM carnation does not spread by asexual reproduction without human intervention; and
- carnation has never been found as a weed in any of the countries that it is cultivated in, including Australia.

### **Transfer of introduced genes to other organisms**

The likelihood of gene transfer from GM carnation to cultivated carnation is negligible because:

- GM carnation like many non GM carnation cultivars are effectively sterile;
- *Dianthus caryophyllus* is not sexually compatible with naturalized carnation species or with other species of the same family, and is geographically isolated from many of the populations of naturalized *Dianthus* species;
- there are no records of gene transfer from non-GM carnation to other plant species;
- natural events of horizontal gene flow from plants to distantly related organisms is extremely rare; and
- the probability of non-homologous recombination of intact plant DNA with the DNA of other organisms is extremely low.

Were this hazard to be realised, it would not pose any risks additional to those posed by the GM carnation itself.

### **THE RISK MANAGEMENT PLAN (KEY LICENCE CONDITIONS)**

Following a thorough and detailed assessment of the risks identified in the above section, it is considered unnecessary to impose any specific management conditions in relation to potential toxicity or allergenicity of GM carnation to humans or to other organisms, weediness, or gene transfer. In making a decision to issue a licence in respect of application number DIR 030/2002, the Regulator considers the licence need only contain minimal conditions to oversight the release on an ongoing basis.

#### **General conditions**

Any licence issued by the Regulator contains a number of general conditions, which may also be relevant to risk management. These include, for example, identification of the persons or classes of person covered by the licence and informing the Regulator if the applicant becomes aware of any additional information about risks to human health or safety or to the environment, or of any unintended effects.

#### **Specific conditions**

It is required that the licence holder provides the OGTR with a testing methodology that can reliably detect the presence of each of the four GM carnation lines and any transferred genetically modified material. The licence holder is required to provide an annual report on the commercial release. This includes information on any adverse impacts on human health

and safety or the environment caused as a result of the GMO or viable material from the GMO. The licence holder must also maintain a written record of production, the site coordinates, and contact details of propagators and growers to whom Florigene gives or sells the GMO, as well as the wholesale distributors of the GMO from whom Florigene receives royalties. These records must be included in the annual report and be made available to the Regulator on request.

### **Monitoring and enforcement of compliance by the OGTR**

It should be noted that as well as imposing licence conditions, the Regulator has additional options for risk management. The Regulator has the legislative capacity to direct a licence holder to take any steps the Regulator deems necessary to protect the health and safety of people or the environment.