



**Australian Government**  
**Department of Health and Ageing**  
**Office of the Gene Technology Regulator**

# **Licence for dealings involving an intentional release of GMOs into the environment**

**Licence No.: DIR 060/2005**

**Licence holder: Florigene Pty Ltd**

**Title: Propagation and Trial of Imported Rose Lines**

Issued: 24 March 2006

Surrendered: 18 November 2008

**More information about this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with this licence. This document can be obtained from the Office of the Gene Technology Regulator website at <http://www.ogtr.gov.au>, or by telephoning the Office on 1800 181 030.**

## **Gene Technology Regulation in Australia**

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form a substantial part of a range of integrated regulatory measures relevant to controlling genetically modified organisms (GMOs) and their use.

The Gene Technology Regulator is required to consult with, and take into account advice from a range of key stakeholders, including regulatory authorities, on risks to human health and safety and to the environment in assessing applications for dealings involving the intentional release of GMOs into the Australian environment.

Other agencies that also regulate GMOs or GM products include FSANZ, APVMA, TGA, NICNAS, NHMRC and AQIS. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

## SECTION 1 INTERPRETATIONS AND DEFINITIONS

This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

In this licence:

- (a) unless defined otherwise in this licence, words and phrases used in this licence have the same meaning as they do in the *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001*;
- (b) words importing a gender include any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing persons include a partnership and a body whether corporate or otherwise;
- (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;
- (f) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;
- (g) specific conditions prevail over standard conditions to the extent of any inconsistency.

In this licence:

**‘Act’** means the *Gene Technology Act 2000* (Cth) and equivalent provisions in corresponding State law.

**‘Annual Report’** means a written report provided to the Regulator within 90 days of each anniversary of the date of issue of this licence containing all the information required by this licence to be provided in the Annual Report.

**‘Clean’** (or **‘Cleaned’**), as the case requires, means the removal and destruction of the GMOs and any Plant Material and in relation to Equipment, the removal of the GMOs and any Plant Material from the Equipment and their destruction.

**‘Compost Heap’** includes the contents of the compost heap, and means a compost heap within the premises of the Australian Roses facility in Silvan, Victoria.

**‘Deal With’** in relation to a GMO means the following,

- (a) conduct experiments with the GMO;
- (b) make, develop, produce or manufacture the GMO;
- (c) breed the GMO

- (d) propagate the GMO;
- (e) use the GMO in the course of manufacture of a thing that is not a GMO;
- (f) grow, raise or culture the GMO;

and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (f).

**‘Equipment’** includes shredding equipment, storage equipment, transport equipment (eg bags, containers, trucks), clothing and tools.

**‘GM’** means genetically modified.

**‘GMOs’** means the genetically modified organisms listed in Attachment B and authorised for release by this licence.

**‘Greenhouse’** means a Greenhouse within the premises of the Australian Roses facility in Silvan, Victoria.

**‘OGTR’** means the Office of the Gene Technology Regulator.

**‘Plant Material’** means viable parts of the GMOs or non-GM rose grown at the Greenhouse or at the Compost Heap including seed, pollen, flowers, leaves, cuttings, rootstock and root ball, whether from the plant itself or derived from or produced by the plant.

**‘Regulator’** means the Gene Technology Regulator.

**‘Rose’** means plants of the species *Rosa X hybrida*, *Rosa multiflora* and *Rosa canina*.

**‘Sign-off’** means a notice in writing from the Regulator stating that the inspection conditions of this licence no longer apply.

**‘Volunteer Plants’** means progeny of the GMOs or non-GM roses at the Greenhouse and Compost Heap or regrowth of previous GM or non-GM rose plants at the Greenhouse and Compost Heap.

## **SECTION 2      GENERAL CONDITIONS**

### **Duration of Licence**

1. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with GMOs are authorised during any period of suspension.

### **Holder of Licence**

2. The holder of this licence ('the licence holder') is Florigene Pty Ltd.

### **Project Supervisor**

3. The Project Supervisor in respect of this licence is identified at Attachment A.
4. The licence holder must immediately notify the Regulator in writing if any of the contact details of the Project Supervisor change.

### **No dealings with GMOs except as authorised by this licence**

5. Persons covered by this licence must not deal with the GMOs except as expressly permitted by this licence.

### **Persons covered by this GMO licence**

6. The persons covered by this licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise authorised by the licence holder to undertake any activity in connection with GMOs grown pursuant to this licence.

### **Informing people of their obligations**

7. The licence holder must inform any person covered by this licence, to whom a particular condition of this licence applies, of the following:

- (a) the particular condition (including any variations of it);
- (b) the cancellation or suspension of the licence;
- (c) the surrender of the licence.

8. The licence holder must provide the Regulator, on the Regulator's written request, signed statements from persons covered by this licence that the licence holder has informed those people of the conditions of this licence that apply to them and that they have understood the conditions and agree to be bound by them.

### **Applicant to notify of circumstances that might affect suitability**

9. The licence holder must immediately, by notice in writing, inform the Regulator of:
- (a) any relevant conviction of the licence holder occurring after the commencement of this licence;

- (b) any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment;
- (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it.

### **Licence holder must provide information on matters related to suitability**

10. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

### **Additional information to be given to the Regulator**

11. It is a condition of a licence that the licence holder inform the Regulator if the licence holder:

- (a) becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or
- (b) becomes aware of any contraventions of the licence by a person covered by the licence;  
or
- (c) becomes aware of any unintended effects of the dealings authorised by the licence.

12. The licence holder must provide the information required by paragraphs (a) (b) and (c) of the immediately preceding condition to the Regulator as soon as practically and reasonably possible and must also include the information in the Annual Report.

### **People dealing with GMOs must allow auditing and monitoring of the dealing**

13. If a person is authorised by this licence to deal with GMOs and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

### **Remaining an Accredited organisation**

14. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and comply with its instrument of accreditation.

### **Notices**

15. The licence holder must provide all notices to the Regulator required to be given by this licence and each notice must be provided in the manner required by Section 10 of this licence.

## **SECTION 3 GROWING THE GMOs**

### **GMOs covered by this licence**

16. The GMOs covered by this licence are described at Attachment B.

### **Permitted dealings**

17. Subject to any applicable conditions, this licence authorises all Dealings with the GMOs.

### **Locations, Growing Seasons and size of trial**

18. The permitted Dealings with the GMOs may be undertaken for two years from the date of issue of the Licence.

19. All Dealings except experiments, transport, shredding and composting of the GMOs and Plant Material must be undertaken in a Greenhouse.

20. The maximum size of the Greenhouse is 100m<sup>2</sup> and no more than one Greenhouse must be used for growing the GMOs at any one time.

21. If the GMOs and/or Plant Material are shredded, shredding must take place either in the Greenhouse or within 5 metres of the Compost Heap.

22. The maximum total size of the Compost Heap is 25m<sup>2</sup>.

23. The licence holder must be able to access and control the Greenhouse and Compost Heap to the extent necessary to comply with this licence, for the duration of the life of the licence.

*Note: Details relating to controlling the Greenhouse and Compost Heap must be provided in the Compliance Management Plan (see Section 9 of this licence)*

### **Measures to manage Gene Flow – Greenhouse**

24. Non-GM roses may be planted and grown in the Greenhouse, but if planted, must be handled and controlled as if they were GMOs for purposes of this licence. All conditions which refer to and apply to a GMO are taken to refer to and apply equally to non-GM roses.

25. Each of the following measures to manage gene flow must be implemented:

- (a) the Greenhouse must be made of framed heavy duty plastic, with a soil floor;
- (b) the GMOs must be grown in pots above the floor;
- (c) the Greenhouse, including ventilation into the Greenhouse, must be insect-proofed;
- (d) any insects observed in the Greenhouse must be killed immediately;
- (e) the Greenhouse floor must be kept clean of Plant Material and weeds;
- (f) all flowers must be harvested before anthers are visible;

- (g) all grafting, propagation and maintenance of GMOs (i.e. pruning, spraying for pests, harvesting flowers) must occur within the Greenhouse;
- (h) the Greenhouse must be secured against unauthorised entry when not occupied; and
- (i) any weeds within 1 metre of the perimeter of the Greenhouse must be removed so as to allow an assessment of the insect-proofing of the Greenhouse.

### **Measures to manage Gene Flow – Compost Heap**

- 26. Plant Material from the GMOs, not used for analysis or storage, must be destroyed by shredding and composting.
- 27. Shredded Plant Material must be deposited on the Compost Heap.
- 28. There must be at least ten metres between the Compost Heap and any non-GM plants including any non-GM plants in other greenhouses.
- 29. The Compost heap must be contained in a manner which does not allow the escape of its contents.
- 30. Containment measures must be implemented to ensure the Compost Heap does not at any time exceed a total of 25 square metres.
- 31. The Compost Heap must remain in the same location throughout the trial.
- 32. Compost, including soil and Plant Material from the Compost Heap must not be removed until after Sign-Off.

## **SECTION 4 DISPOSAL OF THE GMO**

### **Storage, Relocation or Destruction**

- 33. Plant Material from the GMOs must be:
  - (a) stored in a container that is labelled to indicate that it contains Plant Material, within a locked facility that is signed so as to indicate that Plant Material is stored within the facility; or
  - (b) relocated to a facility approved by the Regulator to at least physical containment level 2; or
  - (c) destroyed by shredding and composting.

### **Cleaning**

- 34. Within 14 days of the storage, relocation or shredding and composting of the last GMO, from a Greenhouse, the Greenhouse must be Cleaned.
- 35. Equipment and any areas used to Clean Equipment used in connection with the GMOs at the Greenhouse or Compost Heap must be Cleaned immediately or as soon as practicable after use and before it is used for any other purpose.

## **SECTION 5 USE OF PLANT MATERIAL**

### **Material from the GMOs may be collected**

36. Plant Material may be collected from the Greenhouse for the purpose of conducting experiments on it.

37. Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in their use as food for animals or humans.

### **Transportation of the GMOs and Plant Material**

38. Plant Material may only be transported to the extent necessary to store it, shred and compost it, Clean it from Equipment, relocate it to a facility approved by the Regulator or to physical containment level 2, or relocate it to the Greenhouse from a facility approved by the Regulator or from physical containment level 2.

39. If Plant Material is transported, it must be transported in the manner required by this licence. To the extent that any of the requirements of this licence are inconsistent with the OGTR Guidelines for the Transport of GMOs (2001) the requirements of this licence prevail.

40. Every container used to transport Plant Material must be labelled:

- (a) to indicate that it contains genetically modified rose; and
- (b) with telephone contact numbers for the licence holder and instructions to contact the licence holder in the event that the container is broken or misdirected.

41. The licence holder must have in place accounting procedures to verify whether the same quantity of GMOs or Plant Material sent is delivered and must document routes, methods and procedures used for transportation of GMOs and Plant Material.

## **SECTION 6 USE OF SITE**

### **Inspection**

42. The Compost Heap must be inspected for the existence of Volunteer Plants.

43. Inspection must be performed by a person who is able to recognise Volunteer Plants.

44. Volunteer plants found must be shredded and composted prior to the plant flowering.

45. Inspections of the Compost Heap must begin immediately after the first Plant Material is composted and are to occur at least once every 60 days, until the Regulator has issued a Sign-off.

## **SECTION 7 SIGN OFF**

46. If the Greenhouse has been Cleaned the licence holder may make written application to the Regulator for a Sign Off in respect of the Greenhouse.

47. If inspections of the Compost Heap have been routinely completed for a period of at least 6 months beginning on the day that the last of the Plant Material was added to the Compost Heap, and if inspection records for the Compost Heap show that no Volunteer Plants have been observed in the most recent 6 month inspection period, the licence holder may make written application to the Regulator for Sign off in respect of the Compost Heap.

## **SECTION 8      CONTINGENCY PLANS**

48. Within 30 days of the date of issue of this licence, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event of the unintended presence of the GMOs or Plant Material outside an area that must be inspected.

49. The Contingency Plan must include details of procedures to:

- (a) ensure the Regulator is notified immediately if the licence holder becomes aware of the event;
- (b) destroy any of the GMOs or Plant Material; and
- (c) inspect for and destroy any Volunteer Plants that may exist as a result of the event.

50. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs and Plant Material is discovered outside an area that must be inspected.

## **SECTION 9      COMPLIANCE MANAGEMENT PLAN**

51. Prior to growing the GMOs, a written Compliance Management Plan must be provided to the Regulator. The Compliance Management Plan must describe in detail how the licence holder intends to ensure compliance with each of these conditions and document that compliance and must include:

- (a) a list of the names of all organisations or natural persons who will be persons covered by this licence. Where a name of a person is not known at the time of submitting the Compliance Management Plan the function or position of the person to be covered must be provided.

*Note: Examples of functions or positions are 'Site manager', 'Farm labourer' etc*

- (b) an explanation of how the licence holder has informed, or proposes to inform, each person covered by the licence of the conditions of this licence.
- (c) a description of the responsibilities of the licence holder and of each person covered by the licence in relation to the requirements of this licence.
- (d) a description of how any contracts, agreements, or other enforceable arrangements between the licence holder and persons covered by the licence will allow the licence holder to access and control the Greenhouse and Compost Heap to the extent necessary to comply with this licence, for the duration of the life of the licence or if contracts, agreements, or other enforceable arrangements are not in place how the licence holder proposes to access and control the Greenhouse and Compost Heap to the extent necessary to comply with this licence, for the duration of the life of the licence.
- (e) a description of how the licence holder will comply with the conditions of this licence.

52. Where any of the details of the compliance management plan change, the Regulator must be notified of the changes within 14 days of the change occurring.

## **SECTION 10 REPORTING AND DOCUMENTATION REQUIREMENTS**

53. At least seven days prior to the date on which planting of the GMOs is intended to commence, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the date on which the GMOs are moved to the Greenhouse; and
- (b) the period during which the licence holder considers the GMOs are likely to flower; and
- (c) the GPS coordinates and street address for the Greenhouse.

54. Within seven days of planting of the GMOs, notice of the actual date of planting must be provided to the Regulator.

55. The licence holder must provide the Regulator with a notice of the date on which the first shredding and composting of Plant Material commences. The notice must be given at least 7 days, and not more than 21 days, in advance of the intended date of the first shredding and composting. Any change of intention prior to the intended date must be notified to the Regulator as soon as is reasonably and practically possible.

56. Within seven days of the date on which the Plant Material is first shredded and composted the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the date on which the first GM plant material is shredded and moved to the compost; and
- (b) the GPS coordinates, street address and area for the Compost Heap.

57. The licence holder must provide a notice in writing to the Regulator when the Greenhouse is Cleaned. The notice must be provided to the Regulator within 14 days of the date on which Cleaning concluded.

58. On the request of the Regulator, the Regulator must be provided with written documentation of the procedures in place to ensure continuing compliance with the Cleaning conditions in this licence.

59. The results of inspection activities must be recorded in a logbook or paper file. The findings of the inspections as recorded in the logbook or paper file must be forwarded to the Regulator within 14 days of inspection taking place and must also be included in the licence holder's Annual Report to the Regulator. The logbook or paper file must contain at least the following:

- (a) details of the areas inspected;
- (b) details of the date of inspection;
- (c) the names of the person or persons who undertook the monitoring and details of the experience, training or qualification that enabled them to recognise Volunteer Plants;
- (d) the means of inspection used;

- (e) the number of Volunteer Plants observed, if any;
- (f) details of the development stages reached by the Volunteer Plants, if any; and
- (g) details of methods used to destroy Volunteer Plants, if any.

60. The licence holder must keep records of the number and type of rose plants grown at the Greenhouse as part of the trial, and the number of rose plants from the Greenhouse stored, at the end of the trial.

61. The licence holder must have in place accounting procedures to ensure that the same quantity of GMOs or Plant Material sent is delivered and must document routes, methods and procedures used for transportation of GMOs and Plant Material.

### **Annual Report**

62. The licence holder must provide an Annual Report to the Regulator.

### **Testing methodology**

63. The licence holder must provide a written instrument to the Regulator describing an experimental method that is capable of reliably detecting the presence of the GMOs and the presence of the genetic modifications described in this licence (at Attachment B) in a recipient organism. The instrument must be provided within 30 days of the issuing of this licence.

## ATTACHMENT A

**DIR No: 060/2005**

**\*Full Title:** Propagation and Trial of Imported GM Rose Varieties

### **Organisation Details**

**Postal address:** Florigene Pty Ltd  
1 Park Drive  
BUNDOORA VIC 3083

**Phone No:** (03) 9243 3800

**Fax No:** (03) 9243 3888

### **Project Supervisor Details**

**Surname:** [Personal Information Redacted]

**First Name:** [Personal Information Redacted]

**Title:** [Personal Information Redacted]

**Phone No:** [Personal Information Redacted]

**Fax:** [Personal Information Redacted]

**Email Address:** [Personal Information Redacted]

**Position:** [Personal Information Redacted]

**Organisation:** Florigene Pty Ltd

**Postal Address:** 1 Park Drive  
BUNDOORA VIC 3083

### **IBC Details**

**IBC Name:** Florigene Institutional Biosafety Committee

\* Information that must be included in the Record of GMO and GM Product Dealings.

**GMOs Description**

**Purpose of the Dealing with the GMOs:**

The aim of the proposed release is to propagate three GM rose lines; evaluate their performance including productivity, morphology and viability of the GM rose lines; biochemical analysis of flowers; and generate data to support possible future applications for larger scale releases.

**The GMOs covered by this licence are as follows:**

WKS82/130-4-1,  
WKS82/130-9-1 and  
LA/919-4-10

**\*Parent Organism(s):**

Common Name: Rose  
Scientific Name: *Rosa X hybrida* var. WKS82  
*Rosa X hybrida* var. LA

**Modified Trait(s):**

\*Category: Altered flower colour  
\*Description: Rose plants have been genetically modified to alter flower colour.

**\*Gene Responsible for Conferring the Modified Trait(s):**

**WKS82/130-4-1 and WKS82/130-9-1**

gene encoding flavonoid 3', 5' hydroxylase (*F3'5'H*) from black pansy (*Viola tricolor*)  
gene encoding anthocyanin 5-acyltransferase (*5AT*) from torenia (*Torenia hybrida*)  
*nptII* gene from the bacterium *Escherichia coli* (antibiotic resistance)

**LA/919-4-10**

gene encoding flavonoid 3', 5' hydroxylase (*F3'5'H*) from black pansy (*Viola tricolor*)  
gene encoding dihydroflavonol-4-reductase (*DFR*) from iris (*Iris hollandica*)  
gene encoding dihydroflavonol-4-reductase (*DFR*) from rose (*Rosa X hybrida*) with an inverted repeat  
*nptII* gene from the bacterium *Escherichia coli* (antibiotic resistance)

\* Information that must be included in the Record of GMO and GM Product Dealings.