



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

Licence for dealings involving an intentional release of a GMO into the environment

Licence No.: DIR 090

Licence holder: Florigene Pty Ltd

Title: Commercial release of rose genetically modified for altered flower colour

Issued: 19 June 2009

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the 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 nationally consistent regulatory system controlling the development and use of genetically modified organisms (GMOs).

This licence is issued by the Gene Technology Regulator in accordance with the Gene Technology Act 2000 and, as applicable, Corresponding State Law.

The Gene Technology Regulator is required to consult with, and take into account advice from a range of key stakeholders, including other 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 Food Standards Australia New Zealand, Australian Pesticide and Veterinary Medicine Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme, National Health and Medical Research Council and Australian Quarantine and Inspection Service. 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.

The licence authorises the licence holder and persons covered by the licence to conduct specified dealings with the genetically modified organism(s) listed in Attachment B of this licence.

Dealings permitted by this licence may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Proposed licence conditions

Section 1 Interpretations and Definitions

1. 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.
2. 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 Act and the Regulations
 - (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 with respect to 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 ninety (90) days of each anniversary of issue of this licence containing all the information required by this licence to be provided in the Annual Report.

‘GM’ means genetically modified.

‘GMOs’ means the genetically modified organisms the subject of the dealings authorised by this licence.

‘Hybrid Tea Rose’ means plants of the species *R. x hybrida*, Class Hybrid Tea

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

‘Personal Information’ means information or an opinion (including information forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

Section 2 Licence conditions

Duration of Licence

3. 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

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

Project Supervisor

5. The project supervisor with respect to this licence is the person identified in Attachment A of the licence.

6. The licence holder must immediately notify the Regulator in writing if any of the contact details of the project supervisor change.

GMO covered by this licence

7. The GMO covered by this licence is the organism genetically modified as described in Attachment B.

Permitted dealings

8. Subject to any applicable conditions, the licence holder and persons covered by the licence may:

- (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 the GMO
- (f) grow, raise or culture the GMO
- (g) import the GMO
- (h) transport the GMO
- (i) dispose of the GMO

And may possess, supply or use the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).

9. To the extent that the conditions of any prior licence authorising dealings with the GMO are inconsistent with the conditions of this licence, the conditions of this licence will prevail.

Location

10. This licence permits dealings with the GMO to be conducted in all areas of Australia

Persons covered by this GMO licence

11. Any person, including the licence holder, may conduct any permitted dealing(s) with the GMO

Informing people of their obligations

12. 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.

Applicant to notify of circumstances that might affect suitability

13. 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.

14. The licence holder must notify the project supervisor and all persons to whom a particular licence condition applies that Personal Information collected by the licence holder which is relevant to the administration and/or enforcement of the licence may be released to the Regulator.

Licence holder must provide information on matters related to suitability

15. 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

16. It is a condition of this licence that the licence holder informs the Regulator immediately if the licence holder becomes aware of any of the following:

- (a) 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
- (b) any contraventions of the licence by a person covered by the licence
- (c) any unintended effects of the dealings authorised by the licence.

Note: The Act requires, for the purposes of the above condition that:

- (a) *the licence holder will be taken to have become aware of additional information of a kind mentioned in the above condition if he or she was reckless as to whether such information existed and*
- (b) *the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in the above condition if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

17. 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.

18. If at any time the Regulator requests the licence holder to collect and provide information about any matter to do with the progress of the dealings authorised by this licence, including but not confined to,

- (a) 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, whether or not the licence holder has provided information to the Regulator under condition 16(a)

- (b) any contraventions of the licence by a person covered by the licence, whether or not the licence holder has provided information to the Regulator under condition 16(b)
- (c) any unintended effects of the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 16(c)
- (d) research, including by way of survey, to verify predictions of the risk assessment, or for any purpose related to risks to the health and safety of people, or to the environment
- (e) scientific literature and reports in respect of the GMO authorised by this licence, for a nominated period
- (f) details of any refusals of applications for licences or permits (however described) to deal with the GMO made pursuant to the regulatory laws of a foreign country,

and the request is reasonable, having regard to consistency with the Act and relevance to its purpose, then the licence holder must collect the information and provide it to the Regulator at a time and in the manner requested by the Regulator.

19. If the Regulator invites the licence holder to make a submission on the reasonability of a request by the Regulator to collect and provide information relevant the progress of the GMO, the licence holder may make such a submission to the Regulator within thirty (30) days of receipt of the invitation.

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

20. 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

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

Section 3 Reporting and Documentation Requirements

Annual Report

22. The licence holder must provide an Annual Report to the Regulator. An Annual Report must include the following:

- (a) information about any adverse impacts, unintended effects, or new information relating to risks, to human health and safety or the environment caused by the GMO or material from the GMO
- (b) information on the annual numbers of GM plants grown and GM product (ie cut-flowers) sold Australia-wide
- (c) information about the annual numbers of the GMO grown for non-commercial (eg research) purposes in each State and Territory.

23. The licence holder must keep written records of:

- (a) the names, addresses and contact telephone numbers of all persons or organisations contracted by the licence holder to propagate and/or grow and harvest the GMO
- (b) the site co-ordinates of the locations where the GMO is, or will be, propagated and/or grown and harvested pursuant to contracts described in condition 23(a)
- (c) the total annual number of GM plants propagated and/or grown by persons or organisations pursuant to contracts described in condition 23 (a)
- (d) the total annual numbers of GM cut-flower stems sold.

These records must be included in the annual report and be made available to the Regulator on request.

Testing methodology

24. 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 GMO and the presence of the genetic modifications described in this licence (for details see Attachment B of the licence) in a recipient organism. The instrument must be provided within 30 days of the issuing of this licence.

DIR No: 090

***Full Title:** Commercial release of rose genetically modified for altered flower colour

Organisation Details

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

Phone No: (03) 9243 3800

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: Florigene Pty Ltd
1 Park Drive
BUNDOORA VIC 3083

IBC Details

IBC Name: Florigene Institutional Biosafety Committee

GMO Description***Parent Organism(s):**

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

***Modified trait(s):**

Category: Altered flower colour
 Description: Rose plants have been genetically modified to alter flower colour. The GM rose line also contains a selective marker gene to identify transformed plant tissue.

***Genes responsible for conferring the modified trait:**

Flower colour	gene encoding flavonoid 3', 5' hydroxylase (<i>F3'5'H</i>) from black pansy (<i>Viola tricolour</i>)
Flower colour	gene encoding anthocyanin 5-acyltransferase (<i>5AT</i>) from torenia (<i>Torenia hybrida</i>)
Selectable marker	<i>nptII</i> gene from the bacterium <i>Escherichia coli</i>

Purpose of the dealings with the GMOs:

Florigene applied for a licence for dealings involving the intentional release of one line (WKS82/130-4-1) of Hybrid Tea rose that has been genetically modified (GM) for altered flower colour. The purpose of the release is the ongoing commercial propagation of parent plants and the growing of plants for cut-flowers.

*** Information that must be included in the Record of GM Products and GMO dealings**