



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 068/2006

Licence holder: Florigene Pty Ltd

Title: Limited and controlled release of genetically modified torenia with altered flower colour

Issued: 20 December 2006

Varied: 27 August 2007

Varied: 12 March 2008

Surrendered: 22 September 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).

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 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.

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.

Note about where dealings with GMOs are being undertaken pursuant to this

Information about where the GMOs have been planted pursuant to this licence can be found in a separate document entitled 'DIR 068/2006 Site Details'. This document can be viewed by accessing the document on the OGTR website at <<http://www.otgr.gov.au/ir/dir068.htm>>.

Section 1 Interpretations and Definitions

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 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 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:

- (a) in relation to the Site specified in this licence as requiring Cleaning, the removal and Destruction of the GMOs or Plant Material from the Site, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of GMOs and Plant Material from the Equipment, to the reasonable satisfaction of the Regulator.

'Deal With' in relation to GMOs means one or more of the following as applicable

- (a) conduct experiments with the GMOs
- (b) make, develop, produce or manufacture the GMOs
- (c) breed the GMOs
- (d) propagate the GMOs
- (e) use the GMOs in the course of manufacture of a thing that is not a GMO
- (f) grow, raise or culture the GMOs

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

‘Destroy’ (**‘Destroyed’** or **‘Destruction’**) means as the case requires, killed by

- (a) incineration, or
- (b) removing roots from plants then placing all GM Plant Material directly into sealed plastic bags capable of containing the GMOs without rupture during the course of further dealings and then storing in a lidded waste skip located in the trial site for a period of at least a month, or
- (c) other methods approved in writing by the Regulator.

‘Equipment’ includes the pots in which the GMOs are grown, storage equipment, transport equipment (eg bags, containers, trucks), clothing and tools.

‘GM’ means genetically modified.

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

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

‘Personal Information’ means information or an opinion (including 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.

‘Plant Material’ means any part of the GM or non-GM *Torenia* plants grown at the Site whether viable or not, including, but not limited to, seed, pollen, flowers, stems, leaves, prunings and roots, whether from the plant itself or derived from or produced by the plant.

‘Regulator’ means the Gene Technology Regulator.

‘Sign-off’ means a notice in writing from the Regulator, that the Site has been Cleaned and is free of Volunteer Plants or Plant Material and that the conditions of this licence no longer apply in respect of that Site.

‘Site’ means the area of land in the City of Darebin, Victoria, where the GMOs or other plants are grown pursuant to this licence.

‘Storm or Wind Event’ means any adverse weather that may compromise the integrity of the GMOs or any structures used to support the GMOs, including but not limited to the pots, hanging baskets, support arm or brackets.

‘Torenia’ means plants of the species *Torenia X hybrida*

‘Volunteer Plants’ means progeny of the GM or non-GM *Torenia* plants grown at the Location.

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 the person identified in 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 the 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 the dealings authorised by the 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. Prior to a person covered by this licence conducting any dealings, the licence holder must obtain signed statements from those persons 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. The licence holder must provide the Regulator, on the Regulator's written request, with copies of these signed statements from persons covered by this licence.

9. The immediately preceding condition does not apply to conditions imposed by way of variation to the licence. Where a variation to a licence imposes a new condition, the licence holder must notify persons to whom the condition applies within the time period, and in the manner, stipulated by the Regulator at the time the licence is varied.

10. The licence holder must notify the project supervisor and all persons covered by a licence 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 to notify of circumstances that might affect suitability

11. 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

12. 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

13. It is a condition of this licence that the licence holder informs 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.

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.*

14. The licence holder must provide the information required by paragraphs (a), (b) and (c) of condition 13 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

15. 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.

16. The licence holder must be able to access and control the Site to the extent necessary to comply with this licence, for the duration of the life of the licence.

Remaining an Accredited organisation

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

Notices

18. 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 conditions 51, 52, 53 and 54 of this licence.

Section 3 Growing the GMOs

GMOs covered by this licence

19. The GMOs covered by this licence are described in Attachment B.

Permitted dealings

20. Subject to any applicable conditions, this licence authorises all dealings with the GMOs.

21. Non-GM *Torenia* may be planted and grown at the same location, but if planted, must be handled and controlled as if it were the GMOs (i.e. subject to other applicable conditions elsewhere in this licence). Plant Material from non-GM *Torenia* grown at the location must be handled and controlled as if it were Plant Material from the GMOs (i.e. subject to other conditions elsewhere in this licence).

Location, growing season and size of trial

22. The permitted dealings with the GMOs may be undertaken from September 2007 to May 2009, inclusive, at a single Site within the grounds of La Trobe University (Bundoora), in the City of Darebin, Victoria.

23. All dealings except experiments, transport and Destruction of the GMOs and Plant Material must be undertaken within the Site, which must not exceed an area of 100m².

24. No more than 400 GMOs can be grown as part of the trial.

Notice of intention to plant and of planting

25. The licence holder must, in the manner required by condition 51, give advance notice to the Regulator of an intention to plant the GMOs.

26. The licence holder must, in the manner required by condition 52, give notice to the Regulator of the actual date of planting the GMOs.

Measures to manage spread and persistence of the GMOs

27. Each of the following measures to manage spread and persistence of the GMOs must be implemented:

- (a) GMOs must be grown individually in baskets suspended securely above a concrete or gravel surface;
- (b) the Site must be surrounded by a 2.1m high fence, with lockable gates, which must remain locked at all times except when employee or vehicular access is required to the Site;
- (c) monitoring the area below the baskets during the trial for Plant Material from the GMOs, such as detached stem pieces or prunings, and Destroying any found;
- (d) GM Plant Material must be destroyed if not required for further research or propagation

Section 4 Use of Plant Material, Cleaning and Disposal of Plant Material

Use of GMOs and Plant Material

28. The GMOs and 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 people or in the manufacture of plant products.

Transportation of the GMOs and Plant Material

29. Plant Material may only be transported to the extent necessary to store it, Destroy it, Clean it from Equipment, relocate it to a facility approved by the Regulator or to a physical containment level 2 (PC2) facility, or relocate it to the Site from a facility approved by the Regulator or from a PC2 facility.

30. Subject to conditions 30, Plant Material must be transported according to the *OGTR Guidelines for the Transport of GMOs* as current at the time of transportation.

31. Every container used to transport the GMOs and Plant Material must be labelled:

- (a) to indicate that it contains GM *Torenia*; 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.

Material from the GMOs may be collected

32. Any material from the GMOs including Plant Material, may be collected from the Site for the purpose of conducting experiments on it.

33. Any material from the GMOs including Plant Material, that is collected may be transported off the Site to a facility:

- (a) certified by the Regulator to PC2 for the purpose of conducting experiments on it and/or storage; or
- (b) approved in writing by the Regulator and signed so as to indicate that GM Plant Material is stored within the facility,

and may be experimented on and stored in any one or more of these facilities in accordance with the conditions of certification for those facilities.

34. After any experiments with the material from the GMOs are completed, the Plant Material must be Destroyed.

Note: transport of plant material must comply with conditions 29-31.

Storage, Relocation or Destruction

35. 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

Cleaning

36. Within 14 days of the storage, relocation or Destruction of the last GMO, the Site must be Cleaned.

37. Equipment and any areas used to Clean Equipment used in connection with the GMOs at the Site must be Cleaned immediately or as soon as practicable after use and before it is used for any other purpose.

38. The licence holder must, in a manner required by condition 53, give notice to the Regulator of the date on which Cleaning of the Site concluded.

Section 5 Use of Site, Inspection and Sign off

Inspection

39. The Site, particularly the area under the suspended baskets, must be inspected for the existence of Volunteer Plants or Plant Material during the trial.

40. Inspections of the Site must begin immediately at the commencement of the trial and are to occur on a monthly basis until the last of the GMOs or Plant Material have been removed from the Site.

41. The Site must be inspected as soon as practicable after a Storm or Wind Event during the trial for the presence of any detached Plant Material from the GMOs.

42. Any Volunteer Plants or Plant Material found must be Destroyed.

43. Inspection must be performed by a person who is able to recognise Volunteer Plants or Plant Material from the GMOs.

44. The results of inspection activities must be recorded in a logbook or paper file. The licence holder must, in the manner required by condition 55, provide the Regulator with the findings of the inspections as recorded in the logbook or paper file.

Sign-Off of Site

45. If the Site has been Cleaned, the licence holder may make written application to the Regulator for a Sign Off in respect of the trial.

Section 6 Reporting and Documentation Requirements

Compliance Management Plan

46. 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 would 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 intended to be covered by the licence of the conditions of this licence including conditions related to the collection of Personal Information by the licence holder from the person intended to be covered by the 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 Site to the extent necessary to comply with this licence, for the duration of the life of the licence.

47. Where any of the details of the Compliance Management Plan change, the Regulator must be notified of the changes within fourteen (14) days of the change occurring.

Contingency Plan for Unintended Presence of Plant Material

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 the Site 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.

Notice of intention to plant and of planting

51. At least seven (7) 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 planting of the GMOs is intended to commence;
- (b) the date on which planting of any non-GM *Torenia* at the Site is intended to commence;
- (c) details of the Site where the GMOs will be planted, including the size of the Site, the number of GMOs planted, a street address (including a map of the site), the local government area and GPS coordinates for the Site;
- (d) the period during which the licence holder considers the GMOs are likely to flower;
- (e) the period during which the licence holder considers the GMOs are likely to be Destroyed.

52. Within seven (7) days of planting of the GMOs, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the actual date on which planting of the GMOs occurred;
- (b) details of the Site where the GMOs will be planted, including the size of the Site, the number of GMOs planted, a street address (including a map of the site), the local government area and GPS coordinates for the Site;
- (c) the period during which the licence holder considers the GMOs are likely to flower;
- (d) the period during which the licence holder considers the GMOs are likely to be Destroyed.

Notice of Cleaning

53. The licence holder must provide a notice in writing to the Regulator when the Site is Cleaned. The notice must be provided to the Regulator within fourteen (14) days of the date on which Cleaning of the Site concluded.

54. 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.

Results of inspection activities

55. 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 fourteen (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 or Plant Material from the GMO;
- (d) the means of inspection used;
- (e) the number of Volunteer Plants or Plant Material from the GMOs observed, if any; and
- (f) details of the development stages reached by the Volunteer Plants, if any.

56. The licence holder must keep records of the number and type of Torenia plants grown at the Site as part of the trial, and the number of Torenia plants and Plant Material from the Site stored, at the end of the trial.

Transportation of Plant Material

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

Annual Report

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

Testing methodology

59. 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 (for details see Attachment B) in a recipient organism. The instrument must be provided within thirty (30) days of the issuing of this licence.

ATTACHMENT A

DIR No: 068/2006

***Full Title:** Limited and controlled release of GM Torenia with altered flower colour

Organisation Details

Postal address: 1 Park Drive
Bundoora, Victoria 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 Australia Pty Ltd

Postal Address: 1 Park Drive
Bundoora, Victoria 3083

IBC Details

IBC Name: Florigene IBC

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

GMO Description

Purpose of the dealings with the GMOs:

Florigene applied for a licence to release nine GM Torenia with altered flower colour into the environment on a limited scale and under controlled conditions. The purpose of the trial is to examine their outdoor performance.

The GMOs covered by this licence are as follows:

Torenia with altered flower colour

***Parent Organism(s):**

Common Name: Torenia cv. "summerwave"

Scientific Name: *Torenia X hybrida*

***Modified trait:**

Category: Altered flavonoid biosynthesis

Description: Torenia plants have been genetically modified for altered flower colour

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

Partial gene sequences for altered flower colour:

- anthocyanidin synthase from *Torenia X hybrida*
- flavonoid 3', 5' hydroxylase from *Torenia X hybrida*
- flavonoid 3'-hydroxylase from *Torenia X hybrida*
- flavanone 3 β -hydroxylase from *Torenia X hybrida*

Complete gene sequences for altered flower colour:

- dihydroflavonol-4-reductase from *Pelargonium X hortorum*
- aureusidin synthase from *Antirrhinum majus*
- chalcone-4'-O-glucosyltransferase from *Antirrhinum majus*