



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 084/2008

Licence holder: Florigene Pty Ltd

Title: Limited and controlled release of torenia genetically modified for enhanced phosphate uptake

Issued: 4 September 2008

Varied: 20 October 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 Pesticides and Veterinary Medicines 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.

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

Information about where the GMOs have been planted pursuant to this licence can be found in a separate document entitled 'DIR 084/2008 Site Details'. This document can be viewed by accessing the document on the OGTR website at < <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir084-2008>>.

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 in respect of that word has a corresponding meaning;
 - (g) specific conditions prevail over standard conditions to the extent of any inconsistency.

3. In this licence:

'Act' means the *Gene Technology Act 2000* (Cth) or the corresponding State legislation under which this licence is issued.

'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.

'Clean' (or **'Cleaned'**), as the case requires, means:

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

'Destroy', (or **'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 at the site for a period of at least a month, or
- (c) other methods approved in writing by the Regulator.

'Equipment' includes, but is not limited to, materials used in cultivation practices, clothing and tools.

'GM' means genetically modified.

'GMOs' means the genetically modified organisms that are the subject of the dealings authorised by this licence.

'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.

'Plant Material' means any part of the GMOs or non-GM *Torenia* plants whether viable or not, including, but not limited to, seed, pollen and material cut from the plant as part of standard horticultural practice whether from the plant itself or derived from or produced by the plant.

'Severe weather' means any adverse weather event that may compromise the integrity of the GMOs or any structures used to contain the GMOs.

'Sign-off' means a notice in writing from the Regulator that inspection conditions no longer apply to the Site.

'Site' means an outdoor area of land within the perimeter described in condition 29.

'*Torenia*' means plants of the species *Torenia x hybrida*.

'Volunteer Plants' means progeny of the GMOs or non-GM *Torenia* plants grown at the Site or plants derived asexually from the GMOs or non-GM *Torenia* grown at the Site.

Section 2 General conditions

Duration of Licence

4. 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

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

Project Supervisor

6. The Project Supervisor in respect of this licence is a person named in Attachment A of the licence.

7. 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

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

Persons covered by this GMO licence

9. 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 this licence.

Informing people of their obligations

10. 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.

11. If a particular condition, including any variation of it, applies to a person with respect to a particular dealing, the licence holder must not permit a person covered by this licence to conduct that dealing unless,

- (a) the person has been informed of the condition, including any variation of it; and
- (b) the licence holder has obtained from the person a signed and dated statement that the person:
 - (i) has been informed by the licence holder of the condition and, when applicable, its variation; and
 - (ii) has understood and agreed to be bound by the condition, or its variation; and
 - (iii) has not conducted the dealing without being informed of the condition, or its variation.

12. The licence holder must provide the Regulator, on the Regulator's written request, with copies of the signed and dated statements referred to in the immediately preceding condition.

13. 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.

Applicant to notify of circumstances that might affect suitability

14. 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; and
- (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; and
- (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

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 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 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, 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.

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

18. If a person is authorised by this licence to deal with the 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.

19. 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

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

Notices

21. 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 6 of this licence.

Section 3 Growing the GMOs

GMOs covered by this licence

22. The GMOs covered by this licence are described in Attachment B of the licence.

Permitted dealings

23. The permitted dealings with the GMOs are to plant, grow, propagate, harvest and conduct experiments with the GMOs, and the possession, supply, use, transport and disposal of the GMOs for the purpose of any of the permitted dealings with the GMOs, or in the course of any of these dealings.

Non-GM Plants

24. Non-GM Torenia plants may be grown at the Site, but if planted, must be handled and controlled as if they were the GMOs.

25. Plant Material from non-GM Torenia plants grown at the Site must be handled and controlled as if it were Plant Material from the GMOs.

Limits - Site, growing season and size of trial

26. With respect to the permitted dealings described in condition 23, planting, growing, propagating and harvesting must only be undertaken between October 2008 and May 2010 inclusive, on a single site of maximum total area of 20 m² within the grounds of La Trobe University (Bundoora) in the Victorian local government area of Darebin.

Notice of intention to plant and of planting

27. The licence holder must, in the manner required by condition 54 give advance notice to the Regulator of an intention to plant the GMOs.

28. The licence holder must, in the manner required by condition 55 give notice to the Regulator of the actual date of planting the GMOs.

Controls – planting and growing

29. The Site must be located within the perimeter of existing Florigene greenhouse infrastructure, which is surrounded by a 2.1 metre fence and has lockable gates that must remain locked at all times except when employee or vehicular access is required to the Site.

30. Plants must be grown hydroponically at ground level in plastic tubs, which are secure and capable of containing the plants for the duration of the trial.

Section 4 Use of Plant Material

Experiment and storage

31. Experiments and/or analysis of Plant Material is only permitted if
- (a) the experiment and/or analysis is a notifiable low risk dealing; and
 - (b) the experiment and/or analysis does not involve the feeding of the Plant Material to humans or animals.

Note: A dealing will only be a notifiable low risk dealing if,

- (a) an Institutional Biosafety Committee has been asked to assess whether the proposed dealing is a notifiable low risk dealing; and*
- (b) the Committee has assessed the proposed dealing to be a notifiable low risk dealing; and*
- (c) the person who proposes to undertake the proposed dealing and the project supervisor for the proposed dealing have been notified that the Committee:*

(i) *has assessed the proposed dealing to be a notifiable low risk dealing;*
and

(ii) *considers that the personnel to be involved in the proposed dealing have appropriate training and experience.*

32. Any Plant Material may be collected from the Site for the purpose of conducting experiments and/or analysis on it or any other dealings permitted by this licence.

33. Any Plant Material that is collected for experiments and/or analysis may be transported off the Site for the purpose of conducting experiments on it.

34. Any Plant Material that is collected for experiments and/or analysis may be transported off Site to:

(a) a facility certified by the Regulator to Physical Containment Level 2 (PC2); or

(b) a facility 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, analysed and stored in any one or more of these facilities.

35. Plant Material or waste derived from experiments must be Destroyed as soon as practicable.

Plant Material not to be used as food

36. 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 humans.

Section 5 Transport and Cleaning

Transportation of Plant Material

37. Plant Material may only be transported to the extent necessary to store it, Destroy it, export it, Clean it from Equipment, relocate it to a facility approved by the Regulator or to a PC2 facility for purposes of experiments and/or analysis, or relocate it to the Site from a facility approved by the Regulator or from a PC2 facility.

38. Any Plant Material transported must be transported in accordance with the guidelines for the transportation of GM Plant Material found in the Regulator's *Guidelines for the Transport of GMOs* as current at the time of transportation. Routes, methods and procedures used for this transportation in accordance with this licence must be documented and provided to the Regulator on request.

Cleaning of Site and Equipment

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

40. 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.

41. The Licence holder must, in a manner required by condition 56 give notice to the Regulator of the date on which Cleaning of the Site concluded.

Section 6 Visual Monitoring, Inspection and Sign-off

42. Visual monitoring and inspections must be performed by a person who is able to recognise Volunteer Plants and Plant Material.

43. Any Volunteer Plants and any detached plant parts capable of forming Volunteer Plants, not found to be growing in accordance with the requirements of condition 30 must be Destroyed.

Visual Monitoring

44. The Site, particularly the area surrounding the plastic tubs, must be visually monitored for the existence of Volunteer Plants, and detached plant parts capable of forming Volunteer Plants, and any other non-compliance, during the period that plants are being grown in the tubs. Visual monitoring of the Site must start at the commencement of the trial and is to occur twice per week until the last of the GMOs or Plant Material has been removed from the Site.

Inspection

45. The Site, must be inspected:

- (a) on a monthly basis from the commencement of the trial; and
- (b) as soon as possible after severe weather; and
- (c) if any non-compliances are detected during a visual monitoring

until the last of the GMOs or Plant Materials have been removed from the Site.

46. The licence holder must, in the manner required by condition 58, record the results of inspection activities and forward the results to the Regulator.

47. Inspection requirements do not apply in respect of the Site if the licence holder has received a Sign-off for the Site.

Sign-off

48. If the Site has been Cleaned, the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site.

Section 7 Reporting and Documentation Requirements

Compliance Management Plan

49. 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 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 a Site to the extent necessary to comply with this licence, for the duration of the life of the licence.
50. 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 Plans

51. Within thirty (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.
52. 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.
53. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs or Plant Material is discovered outside an area that must be inspected.

Notice of intention to plant and of planting

54. At least seven (7) days prior to the date on which planting of the GMOs is intended to commence at the Site, 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 is intended to commence;
 - (c) details of the Site where the GMOs will be planted including the size of the Site, a street address and GPS coordinates for the Site; and
 - (d) the identity of the GMOs which are intended to be planted.
55. Within seven (7) days of planting of the GMOs at the Site 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) the actual date on which planting of any non-GM Torenia occurred;
 - (c) details of the Site where the GMOs were planted including the size of the Site, a street address and GPS coordinates for the Site; and
 - (d) the identity of the GMOs which were planted.

Notice of Cleaning

56. 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.

57. 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

58. 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 and detached plant parts capable of forming Volunteer Plants;
- (d) the means of inspection used;
- (e) the number of Volunteer Plants and detached plant parts capable of forming Volunteer Plants observed, if any;
- (f) details of the developmental stages reached by the Volunteer Plants and detached plant parts capable of forming Volunteer Plants, if any;
- (g) details of methods used to Destroy Volunteer Plants and detached plant parts capable of forming Volunteer Plants, if any.

59. The licence holder must keep records of the number and type of GMOs grown at the Site as part of the trial, and the number of any GMOs and/or Plant Materials stored after Cleaning.

Transportation of Plant Material

60. 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

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

Testing methodology

62. 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 of the licence) in a recipient organism. The instrument must be provided within 30 days of the issue of this licence.

ATTACHMENT A

DIR No: 084/2008

***Full Title:** Limited and controlled release of torenia genetically modified for enhanced phosphate uptake

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

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

GMO Description

The GMOs covered by this licence:

Torenia x hybrida containing only the genes, promoters and terminators listed below

*Parent Organism(s):

Common Name: Torenia
 Scientific Name: *Torenia x hybrida*

*Modified trait(s):

Category: Enhanced phosphate uptake
 Description: Torenia plants have been genetically modified to show increased phosphate uptake. All lines also contain a selective marker gene to identify transformed plant tissue.

*Genes responsible for conferring the modified trait:

Increased phosphate uptake *PHR1* gene from *Arabidopsis thaliana*

Selectable marker *nptII* gene from *Escherichia coli*

Promoters and terminators:

E12 35S Ω chimeric promoter (comprising the Cauliflower mosaic virus 35S core promoter and a G-free sequence from the 5' untranslated region of Tobacco mosaic virus)

MAC chimeric promoter (comprising elements from the Cauliflower mosaic virus 35S promoter and the *mannopine synthase* gene promoter from *Agrobacterium tumefaciens*)

Nopaline synthase (nos) gene mRNA promoter region from *Agrobacterium tumefaciens*

A promoter, the identity of which has been declared Confidential Commercial Information

Nopaline synthase (nos) gene mRNA termination region from *Agrobacterium tumefaciens*

Mannopine synthase (mas) gene mRNA termination region from *Agrobacterium tumefaciens*

Purpose of the dealings with the GMOs:

Florigene applied for a licence to release three genetically modified (GM) torenia lines into the environment on a limited scale and under controlled conditions. The purpose of the trial is to conduct proof of concept research involving experiments with the GM torenia lines to assess their capacity to absorb phosphate and slow or repress algal overgrowth in a hydroponic system. The GM torenia will not be used as human food or animal feed.