



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 107

Licence holder: Queensland University of Technology

Title: Limited and controlled release of banana genetically modified for disease resistance

Issued: 12 January 2011

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 accessed on the OGTR website at
<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir107>

Section 1 Interpretations and Definitions

1. 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.

2. In this licence:

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

'Approved Facility' means a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is present within the facility.

'Banana' means commercial cultivars of the species *Musa*.

'Bunch Cover' means standard, plastic tubing used in commercial banana cultivation that is pulled down over the developing fruit bunch.

'Clean' means, as the case requires:

- (a) in relation to an area of land specified in this licence as requiring Cleaning, the Destruction of the GMOs and Plant Material in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, Approved Facilities and the Shadehouse, the removal and Destruction of the GMOs and Plant Material from the Equipment, Approved Facility or Shadehouse, to the reasonable satisfaction of the Regulator.

'Decomposition Container' means a waste bin at the Field Location clearly and visibly labelled to indicate it contains GM Plant Material.

'Destroy' means, as the case requires, killed by a method specified in this licence or, if not specified, by one or more of the following methods:

- (a) cutting down; or

- (b) uprooting; or
- (c) burning/incineration; or
- (d) treatment with herbicide; or
- (e) treatment with organic solvent capable of killing meristematic tissue; or
- (f) decomposition, either on the ground or in a Decomposition Container; or
- (g) shredding; or
- (h) autoclaving; or
- (i) a method approved in writing by the Regulator.

Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, used alone, cutting down may not be sufficient to kill Plant Material remaining after Cleaning and additional treatment(s) may be required.

'Equipment' includes, but is not limited to, storage equipment, transport equipment (e.g. bags, Decomposition Containers, trucks), material used in cultivation practices (e.g. Bunch Covers), clothing, footwear and tools.

'Field Location' means an area of land where the GMOs are planted in the ground and grown.

'GM' means genetically modified.

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

'Isolation Zone' means an area of land extending at least 10 metres in all directions from the outer edge of the Field Location, in which no Bananas may be cultivated while the GMOs are growing in the Field Location.

'Location' means a Field Location or Shadehouse where the GMOs are planted and/or grown pursuant to this licence.

'Logbook' means a written or electronic record containing information required to be collected and maintained by this licence and which is able to be presented to the Regulator on request.

'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 Crop' means the fruit-bearing plant that develops from the propagative material first planted in the ground (as opposed to a Ratoon crop).

'Plant Material' means any part of the GM or non-GM Banana plants grown at a Location, whether viable or not, including, but not limited to, fruit, seed, pollen and material cut from

the plant as part of standard cultural practice, whether from the plant itself or derived from or produced by the plant.

'Ratoon' means the process whereby the main (pseudo)stem that has just borne fruit is cut down and is replaced by a new (pseudo)stem arising from the base of the plant.

'Regulator' means the Gene Technology Regulator.

'Shadehouse' means a lockable area within a permanent structure located approximately 250 m from the Field Location, which is signed so as to indicate that GM Plant Material is present.

'Sign-off' means a notice in writing from the Regulator that post-Cleaning obligations no longer apply in respect of the Field Location.

'Volunteers' means GM or non-GM Banana plants which have not been intentionally grown.

'Waterways' means all permanent natural waterways and man-made waterways that flow into natural waterways.

Note: Irrigation channels, holding dams or storage ponds that do not flow into natural waterways are not considered Waterways for the purpose of this licence.

Section 2 General 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 Queensland University of Technology.

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

Project supervisor

6. The project supervisor in respect of this licence is the person named in Attachment A of the final 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.

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

13. Prior to growing the GMOs, the licence holder must provide the Regulator with an explanation of how the licence holder has informed, or proposes to inform, each person intended to be covered by this licence of the conditions of the licence, including conditions related to the collection of Personal Information by the licence holder.

14. Where any of the details provided under the immediately preceding condition change, the licence holder must notify the Regulator of the changes within 14 days of the change occurring.

15. The licence holder must notify the project supervisor and all persons covered by the 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.

Additional information to be given to the Regulator

16. 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.

17. 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.

18. The licence holder must inform the Regulator, as soon as practically and reasonably possible, 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.*

19. Prior to growing the GMOs, the licence holder must provide to the Regulator:

- (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 list, the function or position of the person to be covered must be provided; and
- (b) 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.

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

20. Where any of the details provided under the immediately preceding condition change, the Regulator must be notified of the changes within 14 days of the change occurring.

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

21. 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.

22. The licence holder must be able to access and control all Locations, Isolation Zones, Approved Facilities or other premises to the extent necessary to comply with this licence, for the duration of the life of the licence.

23. Prior to growing the GMOs, the licence holder must provide to the Regulator a description of how any contracts or other enforceable arrangements will allow the licence holder to access and control a Location, Isolation Zone or other premises to the extent necessary to comply with this licence, for the duration of the life of the licence.

24. Where any of the details provided under the immediately preceding condition change, the Licence holder must notify the Regulator of the changes within 14 days of the change occurring.

Section 3 Growing the GMOs

GMOs covered by this licence

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

Permitted dealings

26. The permitted dealings with the GMOs are to conduct experiments with the GMOs, propagate, grow, culture, transport and dispose of the GMOs, and the possession, supply and use of the GMOs in the course of any of these dealings.

Non-GM Plants

27. Other than the GMOs, only non-GM Banana plants may be grown at a Location, and Plant Material from these plants must be handled and controlled as if they were the GMOs or Plant Material from the GMOs.

Limits - location, timing and size of trial

28. With respect to the permitted dealings described in condition 26, planting, propagating, growing and harvesting must only be undertaken between the date of issue of this licence and November 2014, inclusive, in the local government area of Litchfield Municipality, Northern Territory.

29. Intentional planting and growing of the GMOs must occur at no more than one Field Location and one Shadehouse, such that the maximum combined area does not exceed 1.5 hectares.

Containment measures

30. The outer edge of a Location must not be within 50 metres of a Waterway.

31. The Field Location must be surrounded by an Isolation Zone.

32. The Field Location and Shadehouse must be within a property that is secured against public access by fencing with a lockable gate.
33. The Field Location must have signs no more than 50 m apart around the perimeter to indicate that:
- (a) Bananas at the Field Location are being grown for research or experimental purposes; and
 - (b) Only authorised persons may access the Field Location; and
 - (c) Plant Material must not be removed from the Field Location except as expressly authorised by this Licence.
34. Fruit bunches must be covered with Bunch Covers by the time the young fruit begins to curve upwards. The Bunch Covers may remain open at the bottom but must extend below the fruit so as to discourage access to the fruit by frugivores.
35. During fruiting, there must be weekly checks of the ground below the plants for fallen fruit and any fallen fruit must be Destroyed either by decomposition in a Decomposition Container or by shredding. Once Destroyed, the remains must be placed on the ground within the Field Location.
36. Before the bracts that enclose the male/hermaphrodite flowers have opened, male/hermaphrodite flowers must either be:
- (a) bagged, so as to prevent access of nectar-feeding animals and insects and dispersal of pollen into the environment; or
 - (b) removed from the inflorescences and Destroyed by decomposition in a Decomposition Container, and once Destroyed the remains must be placed on the ground within the Field Location.
37. Male/hermaphrodite flowers that have been bagged and that are no longer required for analysis must be removed and placed in a Decomposition Container before the Field Location is Cleaned. Once Destroyed, the remains must be placed on the ground at the Field Location.
38. All fruit not required for experiments must be harvested from the plants prior to maturation and destroyed either by decomposition in a Decomposition Container or by shredding. Once Destroyed, the remains must be placed on the ground at the Field Location.
39. Each Decomposition Container must remain closed at all times, except when:
- (a) Plant Material is being added; or
 - (b) the contents are being inspected or treated; or
 - (c) Plant Material is being removed; or
 - (d) there is no Plant Material inside.
40. The Shadehouse must remain closed and locked at all times, except when:
- (a) Plant Material is being added; or
 - (b) the contents are being inspected or treated; or
 - (c) Plant Material is being removed; or

- (d) there is no Plant Material inside.

Section 4 Use of Plant Material

Plant Material not to be used in food or animal feed

41. Under this licence, Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals.

Experimentation and storage

42. Plant Material collected or harvested from a Location may, subject to condition 41, be used for experimentation or analysis provided the experimentation and analysis takes place:

- (a) within a Location; or
- (b) in an Approved Facility.

43. Plant Material used for experimentation or analysis must either be stored according to the immediately following condition or Destroyed as soon as practicable after use.

44. Plant Material stored in an Approved Facility must be contained within a sealed, unbreakable container that is clearly labelled so as to identify the contained GMOs.

Note: This licence does not expressly authorise or prohibit any dealings or storage in certified physical containment facilities. Under the Act it is not an offence to deal with a GMO if the dealing is otherwise licensed or if it is an NLRD or an exempt dealing and it complies with all relevant statutory requirements.

Transportation of Plant Material

45. Plant Material may only be transported to the extent necessary to store it, Destroy it, export it, Clean it from Equipment, relocate it for dealings under another relevant authorisation under the Act, conduct experiments on it or transfer it to a Location.

46. Unless occurring under condition 48, transport of GMOs or Plant Material must occur in accordance with the Regulator's *Guidelines for the Transport of GMOs* as current at the time of transportation.

47. Routes, methods and procedures used for all transportation of Plant Material must be documented and provided to the Regulator on request.

48. Transportation of GMOs and Plant Material from the Shadehouse to the Field Location may be undertaken only if:

- (a) the GM Banana plants or containers are labelled as GM Banana or as containing GM Banana; and
- (b) documented procedures are in place to ensure that all GMOs transported can be accounted for.

Section 5 Harvest, Cleaning and Disposal

49. Any fruit harvested at the Field Location must be kept separate from fruit removed from any other Banana crop.
50. Plants may be Ratooned following harvest.
51. Fruit may be harvested from a Plant Crop and a Ratoon crop.
52. Cleaning of:
 - (a) the Shadehouse; and
 - (b) Approved Facilities; and
 - (c) equipment used in connection with the GMOs or Plant Material; and
 - (d) any areas outside the Field Location onto which Plant Material was dispersed during harvest of the GMOs; and
 - (e) any areas used to Clean Equipment used in connection with the GMOs or Plant Material; and
 - (f) any areas used to Destroy the GMOs or Plant Material.

must occur as soon as practicable after use and before they are used for any other purpose, so as to prevent dispersal of Plant Material.

53. The Field Location must be Cleaned once the GMOs are no longer intended to be grown at the Field Location.
54. No plants may be intentionally grown in the Field Location following its Cleaning unless the plants are plants agreed to in writing by the Regulator or the Regulator has issued a Sign-off for the Field Location.

Note: Other conditions of this Licence require the licence holder to make records and give notices to the Regulator in relation to Cleaning (Section 7 – Reporting and Documentation Requirements).

Conditions relating to Disposal of Plant Material waste other than fruit and flowers

55. Non-propagative Plant Material waste at the Field Location must be left as trash to decompose on the ground at the Field Location.
56. Any Plant Material waste at the Field Location containing meristematic tissue must be cut off the main plant at ground level and the meristematic area Destroyed with kerosene, distillate or herbicide. The remains must then be left on the ground at the Field Location.
57. Plant Material waste from the Shadehouse must be transported to the Field Location and left to decompose on the ground. Whole plants from the Shadehouse must first be sprayed with an appropriate herbicide, so as to Destroy meristematic material, before being transferred to the Field Location.
58. Any soil that has been used for growing GM plants in the Shadehouse must be transported to the Field Location and left on the ground.

Section 6 Inspections

59. Following Cleaning, the Field Location must be maintained in a manner appropriate to allow the identification of Volunteers for as long as inspections are required.
60. Inspections must be performed by a person who is able to recognise Volunteers. Details of the experience, training or qualification that enables them to recognise Volunteers must be provided to the Regulator within 14 days of their first inspection.
61. Following Cleaning, the Field Location must be inspected for the existence of Volunteers and any Volunteers found must be Destroyed prior to the plants flowering.
62. Inspections must be conducted at least once every 90 days, commencing on the day of Cleaning of the Field Location and continuing until the Regulator has issued a Sign-off for the Field Location.
63. Inspection requirements do not apply in respect of a Field Location if the licence holder has received a Sign-off for the Field Location.

Note: Results of inspection activities are required to be provided to the Regulator (see Section 7 – Reporting and Documentation Requirements). However, contraventions of licence conditions must be reported as soon as reasonably and practically possible according to Condition 18.

Sign off

64. The licence holder may make written application to the Regulator that inspection conditions no longer apply to the Field Location if:
- (a) inspections have been routinely completed for a period of at least 12 months; and
 - (b) inspection records for the Field Location show that no Volunteers have been observed in the most recent 6 month inspection period.

Section 7 Reporting and Documentation Requirements

Contingency Plan for unintended presence of Plant Material

65. 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.
66. 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; and
 - (b) Destroy any of the GMOs or Plant Material; and
 - (c) inspect for and Destroy any Volunteers that may exist as a result of the event.

67. 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 commencement of the release

68. At least 7 days prior to the date on which the first GMOs are intended to be transported to the Shadehouse, the licence holder must provide a notice in writing to the Regulator which contains details of the Shadehouse, including the area and GPS coordinates.

69. At least 7 days prior to the date on which any GMOs are intended to be transported to the Shadehouse, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the date(s) on which the GMOs are intended to be placed in the Shadehouse; and
- (b) the identity of the GMOs which are intended to be grown in the Shadehouse; and
- (c) the period during which the licence holder considers the GMOs will be transported from the Shadehouse to the Field Location.

70. Within 7 days of the GMOs being placed in the Shadehouse, the licence holder must provide a notice in writing to the Regulator which indicates the actual date(s) on which the GMOs arrived and any changes in the details required to be provided under the immediately preceding condition.

Notice of intention to plant and of planting

71. At least 7 days prior to the date on which planting of the first GMOs at the Field Location is intended to commence, the licence holder must provide a notice in writing to the Regulator which contains details of the Field Location where the GMOs will be planted, including the size and GPS coordinates for the Field Location.

72. At least 7 days prior to the date on which planting of any GMOs at the Field Location is intended to commence, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the date(s) on which planting of the GMOs is intended to commence; and
- (b) the identity of the GMOs which are intended to be planted.

73. Within 7 days of planting of the GMOs, the licence holder must provide a notice in writing to the Regulator which indicates the actual date(s) on which planting of the GMOs occurred and any changes in the details required to be provided under the immediately preceding condition.

Notice of final Cleaning the Shadehouse

74. The licence holder must provide a notice in writing to the Regulator once GMOs are no longer intended to be grown or housed in the Shadehouse under this licence, indicating the intended date of Cleaning of the Shadehouse. This notice must be provided at least 7 days, and not more than 21 days, in advance of the intended date of Cleaning set out in the relevant

notice. Any change of intention prior to the intended Cleaning date must be notified to the Regulator as soon as is reasonably and practically possible.

75. Within 14 days of the date on which final Cleaning of the Shadehouse is completed, the licence holder must provide a notice in writing to the Regulator indicating the date or dates on which Cleaning was undertaken.

Notice of Cleaning the Field Location

76. The licence holder must provide a notice in writing to the Regulator of intention to Clean the Field Location. This notice must be provided at least 7 days, and not more than 21 days, in advance of the intended date of Cleaning set out in the relevant notice. Any change of intention prior to the intended Cleaning date must be notified to the Regulator as soon as is reasonably and practically possible.

77. Within 7 days of commencement of Cleaning of the Field Location, the licence holder must provide the actual date or dates of commencement of Cleaning of the Field Location.

78. Within 14 days of the date on which Cleaning of the Field Location is completed, the licence holder must provide a notice in writing to the Regulator indicating the date or dates on which Cleaning was undertaken, and a description of how the Field Location is intended to be used during the first 2 years following its Cleaning.

79. On the request of the Regulator, the licence holder must provide written documentation of the procedures in place to ensure compliance with the Cleaning conditions in this licence.

Notices of inspection activities

80. The results of all inspection activities must be recorded in a Logbook and must contain at least the following:

- (a) the date(s) of inspection; and
- (b) the names of the person or persons who undertook the inspection; and
- (c) details of the areas inspected; and
- (d) details of current land use (e.g. type of crop being grown) and of recent land management practices (e.g. irrigation, cultivation or spraying) applied in the areas inspected; and
- (e) details of any rainfall events at the Field Location that occur after its Cleaning, including measurements of any rainfall at or near the Field Location;
- (f) the number of Volunteers observed, if any; and
- (g) details of the development stages reached by the Volunteers, if any; and
- (h) details of methods used to Destroy Volunteers, if any, and the actual date(s) of Destruction, if different from the date of inspection.

81. The results of the inspections as recorded in the Logbook must be forwarded to the Regulator within 35 days of inspection taking place.

Extreme weather conditions

82. The licence holder must immediately, by notice in writing, inform the Regulator of any extreme weather conditions such as cyclones or flooding that have affected a Location, or that are expected to affect a Location, whilst the GMOs are growing at a Location or whilst subject to inspection requirements.

Other records to be kept

83. The licence holder must keep records of any Cleaning of the Shadehouse in a Logbook, and provide the information in the record to the Regulator upon request.

84. The licence holder must keep records of the type of GM Banana lines grown at each Location as part of the trial, and the area planted to each GM Banana line.

Testing methodology

85. 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 in a recipient organism. The detection method must be capable of reliably distinguishing between the GMOs described in this licence. The instrument must be provided within 30 days of the issuing of this licence.

DIR No: 107***Full Title:** Limited and controlled release of banana genetically modified for disease resistance**Organisation Details****Postal address:** Centre for Tropical Crops and Biocommodities
Queensland University of Technology (Gardens Point Campus)
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BRISBANE QLD 4001**Phone No:** (07) 3138 1326**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:** *[Personal Information Redacted]***Postal Address:** *[Personal Information Redacted]***IBC Details****IBC Name:** QUT Institutional Biosafety Committee

GMO Description

GMOs covered by this licence:

Lines of *Musa* spp. genetically modified by introduction of only the genes and genetic elements listed below.

***Parent Organisms:**

Common Names: Banana

Scientific Names: *Musa acuminata* cvs Williams, Grande Naine and Dwarf Cavendish
M. acuminata x *M. balbisiana* cv Lady Finger

***Modified traits:**

Categories: Disease resistance
Reporter gene expression
Antibiotic resistance

Description: Banana plants have been genetically modified for disease resistance or reporter gene expression by *Agrobacterium*-mediated transformation. Up to 151 lines of GM banana may be released. Each line contains one or two of the genes described in Table 1, as well as the antibiotic resistance marker gene *nptII*.

***Genetic elements responsible for conferring the modified traits:**

Refer to Table 1 of this attachment.

Purpose of the dealings with the GMOs:

Queensland University of Technology has applied for a licence to release up to 151 lines of genetically modified (GM) banana into the environment on a limited scale and under controlled conditions. The purpose of the trial is to conduct experiments to assess whether expression of the introduced genes for disease resistance results in altered disease response and/or development of the GM bananas. Material from the GM banana plants will not be used in human food or animal feed.

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

Table 1. The genes introduced into the GM banana lines proposed for release.

Gene	Gene – full name	Source	Intended function
<i>RGC2</i>	Resistance gene candidate-2	<i>Musa sp.</i>	<i>Fusarium</i> resistance
<i>RGC5</i>	Resistance gene candidate-5	<i>Musa sp.</i>	<i>Fusarium</i> resistance
<i>Ced-9</i>	Cell death abnormality gene-9	<i>Caenorhabditis elegans</i>	Inhibition of apoptosis
<i>mCed-9</i>	Cell death abnormality gene-9, plant codon optimised	<i>C. elegans</i>	Inhibition of apoptosis
<i>p35</i>	<i>p35</i> gene	<i>Autographa californica nucleopolyhedrovirus</i> (Baculovirus)	Inhibition of apoptosis
<i>Sf-IAP</i>	Inhibitor of apoptosis	<i>Spodoptera frugiperda</i>	Inhibition of apoptosis
<i>AtBag4</i>	Bcl-2-associated anthanogene-4	<i>Arabidopsis thaliana</i>	Inhibition of apoptosis
<i>OsBag4</i>	Bcl-2-associated anthanogene-4	<i>Oryza sativa</i>	Inhibition of apoptosis
<i>p65</i>	<i>p65</i> gene (heat shock protein-70 homologue)	<i>Citrus tristeza virus</i>	Inhibition of apoptosis
<i>p61</i>	<i>p61</i> gene (heat shock protein-90 homologue)	<i>Citrus tristeza virus</i>	Inhibition of apoptosis
<i>AtBI-1</i>	Bax inhibitor	<i>A. thaliana</i>	Inhibition of apoptosis
<i>uidA</i>	β -glucuronidase gene	<i>Escherichia coli</i>	Reporter gene

Table 2. Gene constructs used to generate the GM banana lines proposed for release.

Subgroup or Cultivar	Identity of construct	Promoter (source) ^{1,2}	Additional genetic elements ¹	Gene(s) of interest	Terminator ²	Max. lines per construct	Max. total no. of plants
Cavendish	pPTN261	<i>Ubi</i>	<i>Ubi</i> intron and TEV leader sequence	<i>Ced-9</i>	<i>CaMV35S</i>	9	90
	pYC35	<i>RGC2</i> (<i>Musa sp</i>)	-	<i>RGC2</i>	<i>Nos</i>	2	20
	pYC16	<i>Nos</i>	-	<i>RGC2</i>	<i>Nos</i>	7	70
Lady Finger	pPTN261	<i>Ubi</i>	<i>Ubi</i> intron and TEV leader sequence	<i>Ced-9</i>	<i>CaMV35S</i>	3	30
	pYC10	<i>Ubi</i>	<i>Ubi</i> intron	<i>Ced-9</i>	<i>Nos</i>	10	100
	pYC11	<i>Ubi</i>	<i>Ubi</i> intron	<i>mCed-9</i>	<i>Nos</i>	10	100
	pYC13	<i>Nos</i>	-	<i>RGC5</i>	<i>Nos</i>	10	100
	pYC14	<i>Ubi</i>	<i>Ubi</i> and <i>Cat</i> (castor bean) introns	<i>uidA</i>	<i>Nos</i>	10	100
	pYC15	<i>Nos</i>	-	<i>uidA</i>	<i>Nos</i>	10	100
	pYC17	<i>Ubi</i>	<i>Ubi</i> intron	<i>Sf-IAP</i>	<i>Nos</i>	10	100
	pYC18	<i>Ubi</i>	<i>Ubi</i> intron	<i>AtBI-1</i>	<i>Nos</i>	10	100
	pYC19	<i>Ubi</i>	<i>Ubi</i> intron	<i>p35</i>	<i>Nos</i>	10	100
	pYC20	<i>Ubi</i>	<i>Ubi</i> intron	<i>p61</i>	<i>Nos</i>	10	100
	pYC21	<i>Ubi</i>	<i>Ubi</i> intron	<i>p65</i>	<i>Nos</i>	10	100
	pYC22	<i>Ubi</i>	<i>Ubi</i> intron	<i>OsBag4</i>	<i>Nos</i>	10	100
pYC23	<i>Ubi</i>	<i>Ubi</i> intron	<i>AtBag4</i>	<i>Nos</i>	10	100	
pYC24	<i>Ubi</i> <i>Ubi</i>	<i>Ubi</i> intron <i>Ubi</i> intron	<i>AtBag4</i> <i>p65</i>	<i>Nos</i> <i>Nos</i>	10	100	

¹ The *Ubi* promoter and intron are derived from *Zea mays* (maize).

² The *Nos* promoter and terminator are derived from *Agrobacterium tumefaciens*.