



**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 109**

**Licence holder: Queensland University of Technology**

**Title: Limited and controlled release of banana genetically modified for enhanced nutrition**

**Issued: 3 August 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/dir>

## **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.

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

**'Bunch Cover(s)'** 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, the Shadehouse and the Packing Shed, the removal and Destruction of the GMOs and Plant Material from the Equipment or the Shadehouse or the Packing Shed, to the reasonable satisfaction of the Regulator.

**'Decomposition Container'** means one or more lockable waste bins at the Field Location clearly labelled to indicate that they contain GM Plant Material.

**'Destroy'** means, as the case requires, killed 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 individually, cutting down may not be sufficient to kill Plant Material remaining after final Harvest 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.

**'Harvest'** means the removal of bunch(es) of fruit from plants at a Field Location.

**'Location'** means a Field Location or the 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.

**'Package'** means banana fruit packed in a sealed, sturdy garbage bag which in turn is enclosed within a sealed plain cardboard carton.

**'Packing Shed'** means a lockable permanent structure located approximately 300 m from the Field Locations which is signed to indicate that GM Plant Material is present.

**'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. Subsequent fruit develops from a Ratoon crop (see below).

**‘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, permanent structure located approximately 500 m from the Field Location which is signed to indicate that GM Plant Material is present.

**‘Sign-off’** means a notice in writing from the Regulator, in respect of a Field Location, that post-final Harvest obligations no longer apply in respect of that Field Location.

**‘Site’** means the aggregate of both of the Field Locations, Shadehouse and the Packing Shed.

**‘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. In the case of transport of Plant Material, paragraph (a) of condition 10 will be satisfied by compliance with the labelling requirements of condition 48 of this licence.

12. Condition 49 is exempted from the operation of paragraph (b) of condition 13.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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***

18. 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.

19. 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.

20. 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.*

21. 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.*

22. 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***

23. 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.

24. The licence holder must be able to access and control all the Field Locations and the Packing Shed and Shadehouse or other premises to the extent necessary to comply with this licence, for the of the licence.

25. 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 all the Field Locations and the Packing Shed or other premises to the extent necessary to comply with this licence, for the duration of the life of the licence.

26. 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***

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

***Permitted dealings***

28. 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.

***Plants that may be grown at Locations***

29. The only plants permitted to be grown at a Location are:

- the GMOs
- non-GM Banana plants

***Handling of Non-GM Plants***

30. Non-GM Banana plants 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***

31. With respect to the permitted dealings described in condition 28, propagating and growing must only be undertaken between August 2011 and August 2013, inclusive, in the Shire of Johnstone, Queensland.

32. Intentional planting and growing of the GMOs must occur at no more than two Field Locations and one Shadehouse, such that the maximum combined area does not exceed 2.0 hectares.

### ***Containment measures***

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

34. The Field Location must have signs no more than 50 metres apart around the perimeter to indicate that:

- (a) GM Bananas are being grown at the Field Location for research or experimental purposes; and
- (b) only authorised persons may access the Field Location or remove Plant Material as pursuant to these licence conditions.

35. 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 Locations.

36. 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.

37. During fruiting, there must be weekly checks of the ground below the plants for fallen fruit and any fallen fruit must be Destroyed. Once Destroyed, any remains must be placed on the ground within the Field Locations.

38. All fruit not required for experiments must be Harvested from the plants prior to maturation and Destroyed. Once Destroyed, the remains must be placed on the ground within the Field Locations.

39. Any excess Plant Material not required for experiments must be Destroyed and once Destroyed any remains must be placed on ground within the Field Locations.

40. The Packing Shed must not be used for Packing non-GM banana while GM banana fruit are being Packaged or stored.

41. The Shadehouse, the Packing Shed and Decomposition Containers must remain locked at all times, except when Plant Material:

- (a) is being added; or

- (b) is being handled; or
- (c) is being removed; or
- (d) the contents are being inspected; or
- (e) there is no un-Packaged GMOs or Plant Material inside.

## **Section 4 Use of Plant Material**

*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.*

### **Plant Material not to be used in food or animal feed**

42. The GMOs and 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.

*Note: Nothing in this licence condition prevents the licence holder from applying for another licence to conduct controlled human nutritional experiments.*

### **Experimentation and storage**

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

- (a) a Location; or
- (b) the Packing Shed; or
- (c) a facility approved in writing by the Regulator; or
- (d) the Waite Analytical Services, Floor/Room LG11, Waite Building, Waite Campus, University of Adelaide, Glen Osmond, South Australia 5064.

44. 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.

45. Plant Material must be stored in a sealed, unbreakable container that is clearly labelled so as to identify the contained GMOs.

### **Transportation of Plant Material**

46. Plant Material may only be transported to the extent necessary to store it, Destroy it, Clean it from equipment, export it, pack it, conduct experiments or analysis on it, transfer it to a Location or relocate it for the purpose of conducting dealings pursuant to another relevant authorisation under the Act.

47. Unless transported in accordance with conditions 48 and 49, or 50, transport of GMOs and Plant Material must occur in accordance with Section 1.2 of the Regulator's *Guidelines of the Transport, Storage and Disposal of GMOs* as current at the time of transportation.

48. GM banana fruit to be transported outside the Site under condition 49 must be Packaged so as to prevent any dispersal of the GM fruit during transport, and the Package must be labelled so as to inform the Package handler:

- (a) that the Package contains genetically modified (GM) Plant Material authorised under the *Gene Technology Act 2000* that is for research purposes only; and
- (b) that the Package holder is covered by licence DIR 109 under the *Gene Technology Act 2000* to transport the genetically modified (GM) Plant Material from [the specified transport departure point] to [the specified transport destination point] and to possess that genetically modified organism for the purposes of, or in the course of, that transport, but is not authorised to conduct any other dealings with the plant material; and
- (c) that the contents of the Package must not be consumed by humans or animals; and
- (d) that the package handler must not open the package or disseminate the GM Plant Material; and
- (e) that the licence holder or the intended recipient of the Package must be contacted immediately in case the Package is missing or broken; and
- (f) of the name and contact numbers for the licence holder and the intended recipient.

49. Packaged GM banana fruit may be transported outside the Site only if documented procedures are in place to ensure that all Packages can be accounted for at the destination, and any loss of GM fruit or non-delivery can be detected.

50. Transportation of GMOs and Plant Material within the Site may be undertaken if:

- (a) the pots or any other container used for the purpose are labelled so as to indicate that GM Plant Material is present;
- (b) documented procedures are in place to ensure that no material is lost en route; and
- (c) propagative Plant Material is enclosed within a sealed container.

51. Methods and procedures used for all transportation of Plant Material must be provided to the Regulator on request.

## **Section 5 Harvest, Cleaning and Disposal**

52. Fruit Harvested at the Field Locations must be kept separate from other fruit.

53. Plants may be Ratooned following Harvest.

54. Cleaning of:

- (a) the Shadehouse; and
- (b) the Packing Shed; and

- (c) any areas used during Harvest of the GMOs; and
- (d) any areas used to Clean Equipment used in connection with the GMOs or Plant Material; and
- (e) any areas used to Destroy the GMOs or Plant Material;

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

55. The Field Location must be Cleaned once the GMOs are no longer intended to be grown at a Field Location.

56. No plants may be intentionally grown at a 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**

57. Non-propagative Plant Material waste at the Field Location must be left as trash to decompose on the ground at a Field Location.

58. Any Plant Material waste at a 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.

59. Non-propagative Plant Material waste from the Shadehouse and the Packing Shed must be transported to a Field Location and left to decompose on the ground.

60. Suckers and whole plants from the Shadehouse must first either be sprayed with an appropriate herbicide or decomposed in Decomposition Containers, so as to Destroy meristematic material. Once Destroyed, the remains must be placed on the ground within the Field Locations.

61. Any soil that has been used for growing GM plants in the Shadehouse must be transported to a Field Location and left on the ground.

## **Section 6 Inspections**

62. Following Cleaning, a Field Location must be maintained in a manner appropriate to allow the identification of Volunteers for as long as inspections are required.

63. 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.

64. Following Cleaning, a Field Location must be inspected for the existence of Volunteers and any Volunteers found must be Destroyed prior to the plants flowering.

65. Inspections must be conducted at least once every 90 days, commencing on the day of Cleaning of a Field Location and continuing until the Regulator has issued a Sign-off for the Field Location.

66. 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).*

### **Sign off**

67. The licence holder may make written application to the Regulator that inspection conditions no longer apply to a 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**

68. 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.

*Note: Any Packaged GM banana fruit misplaced or lost during transport outside the Site constitutes an event.*

69. 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) recover and 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.

70. 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**

71. 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 size and GPS coordinates.

72. 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.

73. 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***

74. 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.

75. 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.

76. 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 of the Shadehouse, the Packing Shed and the Field Locations***

77. The licence holder must provide notices in writing to the Regulator indicating the intended date of Cleaning of:

- (a) the Shadehouse once GMOs are no longer intended to be grown or housed in the Shadehouse under this licence; or
- (b) the Packing Shed once Plant Material are no longer to be packed in the Packing Shed under this licence; or
- (c) a Field Location

78. Notices provided under the immediately preceding condition 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 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.

79. Within 14 days of the date on which Cleaning of the Shadehouse or the Packing Shed or a 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. For a Field Location, a description of how the Field Location is intended to be used during the first year following its Cleaning must also be provided.

80. 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***

81. 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) the number of Volunteers observed, if any; and
- (f) details of the development stages reached by the Volunteers, if any; and
- (g) details of methods used to Destroy Volunteers, if any, and the actual date(s) of Destruction, if different from the date of inspection.

82. 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***

83. 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 or are expected to affect a Site whilst the GMOs are growing at the Site or whilst subject to inspection requirements.

### ***Other records to be kept***

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

85. The licence holder must keep records of any checks for fallen fruit in a Logbook, and provide the information in the record to the Regulator upon request.

86. 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***

87. 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 categories of GMOs described in this licence. The instrument must be provided within 30 days of the issuing of this licence.



**DIR No: 109**

**\*Full Title:** Limited and controlled release of banana genetically modified for enhanced nutrition

**Organisation Details**

**Postal address:** Centre for Tropical Crops and Biocommodities  
Queensland University of Technology (Gardens Point Campus)  
GPO Box 2434  
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 Dwarf Cavendish and Williams  
*M. accuminata* x *M. balbisiana* cv Lady Finger

#### \*Modified traits:

Categories: Enhanced nutrition  
 Reporter gene expression  
 Antibiotic resistance

Description: Banana plants have been genetically modified for enhanced nutrition or reporter gene expression by *Agrobacterium*-mediated transformation. Up to 1241 lines of GM banana may be released. The introduced genes are listed in Table 1. Each line contains the antibiotic resistance marker gene *nptII* plus from one up to three genes described in Table 1. The combinations of genes and regulatory sequences are listed in the Table 2 along with other genetic elements, if any.

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

Refer to Table 1 of this attachment.

### Purpose of the dealings with the GMOs:

The purpose of the trial is to assess pro-vitamin A and/or iron levels in the GM banana fruit and agronomic performance of GM banana plants grown under field conditions. The GM bananas will not be permitted to enter the commercial human or animal food supply chains.

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

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

Gene	Gene – full name	Source	Intended function
<i>DXS</i>	Deoxy-xylulose-5-phosphate synthase	Thale cress ( <i>Arabidopsis thaliana</i> )	pro-vitamin A biosynthesis
<i>PsyB73</i>	Phytoene synthase 1	Maize ( <i>Zea mays</i> ) inbred line B73	pro-vitamin A biosynthesis
<i>Psy1Q60</i>	Phytoene synthase 1	Maize ( <i>Z. mays</i> ) inbred line Q60	pro-vitamin A biosynthesis
<i>APsy2a</i>	Phytoene synthase 2	Banana ( <i>Musa spp.</i> ) cultivar Asupina	pro-vitamin A biosynthesis
<i>CrtI</i>	Phytoene desaturase	<i>Erwinia uredovora</i>	pro-vitamin A biosynthesis
<i>LYCB</i>	Lycopene $\beta$ -cyclase	Rice ( <i>Oryza sativa</i> )	pro-vitamin A biosynthesis
<i>Ferritin</i>	Ferritin	Wild soybean ( <i>Glycine soja</i> )	Fe-assimilation
<i>NAS</i>	Nicotianamine synthase	Rice ( <i>O. sativa</i> )	Fe-assimilation
<i>FEA1</i>	Fe-assimilation 1	<i>Chlamydomonas reinhardtii</i>	Fe-assimilation
<i>uidA</i>	$\beta$ -glucuronidase gene	<i>Escherichia coli</i>	Reporter gene
<i>nptII</i>	Neomycin phosphotransferase type II gene	<i>E. coli</i>	Selectable marker

**Table 2.** Description of constructs to be used to generate the GM bananas, numbers of GM banana lines and plants authorised for release.

Cultivar	Construct(s)	Gene(s)	Promoter(s) <sup>1</sup>	Terminator(s) <sup>2</sup>	Additional genetic elements	Max. lines	Max. total no. of plants
Dwarf Cavendish	pCAM-Exp1-APsy2a	<i>APsy2A</i>	<i>Exp1</i>	<i>Nos</i>		5	50
	pCAM-ACO-APSy2a	<i>APsy2A</i>	<i>ACO</i>	<i>Nos</i>		5	50
	pCAM-Ubi-APSy2a	<i>APsy2A</i>	<i>Ubi</i>	<i>Nos</i>		2	20
	pCAM-Exp1-PsyB73	<i>PsyB73</i>	<i>Exp1</i>	<i>Nos</i>		5	50
	pCAM-ACO- PsyB73	<i>PsyB73</i>	<i>ACO</i>	<i>Nos</i>		5	50
	pCAM-Ubi-PsyB73	<i>PsyB73</i>	<i>Ubi</i>	<i>Nos</i>		4	40
	pCAM-ACO-APSy2a pBin-Exp1-CrtI	<i>APsy2A</i> <i>CrtI</i>	<i>ACO</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>	CMSSP <sup>3</sup>	5	50
	pCAM-ACO-PsyB73 pBin-Exp1-CrtI	<i>PsyB73</i> <i>CrtI</i>	<i>ACO</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		5	50
	pCAM-Exp1-Ferritin	<i>Ferritin</i>	<i>Exp1</i>	<i>Nos</i>		5	50
	pCAM-Exp1-APsy2a	<i>APsy2A</i>	<i>Exp1</i>	<i>Nos</i>		5	50
Lady Finger	pCAM-ACO-APSy2a	<i>APsy2A</i>	<i>ACO</i>	<i>Nos</i>		5	50
	pCAM-Exp1-PsyB73	<i>PsyB73</i>	<i>Exp1</i>	<i>Nos</i>		5	50
	pCAM-ACO- PsyB73	<i>PsyB73</i>	<i>ACO</i>	<i>Nos</i>		5	50
	pCAM-Exp1-APsy2a	<i>APsy2A</i>	<i>Exp1</i>	<i>Nos</i>		5	50
Williams	pOPT-A	<i>Psy1Q60</i> <i>CrtI</i>	<i>Exp1</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>	Rbcs-CTP <sup>4</sup>	10	10
	pOPT-B	<i>Psy1Q60</i> <i>CrtI</i>	<i>Exp1</i> <i>Exp4</i>	<i>Nos</i> <i>Nos</i>		10	10
	pOPT-C	<i>Psy1Q60</i> <i>CrtI</i> <i>Ferritin</i>	<i>Exp1</i> <i>Exp1</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i> <i>Nos</i>		10	10
	pOPT-D	<i>APsy2A</i> <i>CrtI</i>	<i>Exp1</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		10	10
	pOPT-F	<i>APsy2A</i>	<i>Exp4</i>	<i>Nos</i>		30	30
	pOPT-G	<i>uidA-Cat</i>	<i>Exp1</i>	<i>Nos</i>	<i>Cat</i> <sup>5</sup>	30	30
	pOPT-H	<i>Psy1 Q60</i> <i>Ferritin</i>	<i>ACS</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		30	30
	pOPT-I	<i>Psy1 Q60</i>	<i>ACS</i>	<i>Nos</i>		30	30
	pOPT-J	<i>Psy1 Q60</i>	<i>Exp1</i>	<i>Nos</i>		30	30
	pOPT-K	<i>APsy2A</i>	<i>Exp1</i>	<i>Nos</i>		30	30
	pOPT-L	<i>Psy1 Q60</i> <i>Ferritin</i>	<i>Exp1</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		30	30
	pGen2-A	<i>Apsy2a</i>	<i>Exp1</i>	<i>Nos</i>		30	30

pGen2-B	<i>Psy1 Q60</i>	<i>Exp1</i>	<i>Nos</i>		30	30
pGen2-C	<i>Ferritin</i>	<i>Exp1</i>	<i>Nos</i>		30	30
pGen2-D	<i>Ferritin</i>	<i>MT2a</i>	<i>Nos</i>		30	30
pGen2-E	<i>Ferritin</i>	<i>ACO</i>	<i>Nos</i>		30	30
pGen2-F	<i>Apsy2a</i>	<i>MT2a</i>	<i>Nos</i>		30	30
pGen2-G	<i>Apsy2a</i>	<i>Ext</i>	<i>Nos</i>		30	30
pGen2-CA	<i>Ferritin</i> <i>Apsy2a</i>	<i>Exp1</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen2-DA	<i>Ferritin</i> <i>Apsy2a</i>	<i>MT2a</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen2-AF	<i>Apsy2a</i> <i>Apsy2a</i>	<i>Exp1</i> <i>MT2a</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen2-CD	<i>Ferritin</i> <i>Ferritin</i>	<i>Exp1</i> <i>MT2a</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen3-EA	<i>Ferritin</i> <i>Apsy2a</i>	<i>ACO</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen3-H	<i>DXS</i>	<i>Exp1</i>	<i>Nos</i>		30	30
pGen2-I	<i>LYCB</i>	<i>Exp1</i>	<i>Nos</i>		30	30
PGen3-HI	<i>DXS</i> <i>LYCB</i>	<i>Exp1</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen3-HA	<i>DXS</i> <i>Apsy2a</i>	<i>Exp1</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen3-AI	<i>Apsy2a</i> <i>LYCB</i>	<i>Exp1</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen3-HAI	<i>DXS</i> <i>Apsy2a</i> <i>LYCB</i>	<i>Exp1</i> <i>Exp1</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i> <i>Nos</i>		30	30
pGen3-J	<i>DXS</i>	<i>MT2a</i>	<i>Nos</i>		30	30
pGen3-K	<i>LYCB</i>	<i>MT2a</i>	<i>Nos</i>		30	30
pGen-JK	<i>DXS</i> <i>LYCB</i>	<i>MT2a</i> <i>MT2a</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen3-JF	<i>DXS</i> <i>Apsy2a</i>	<i>MT2a</i> <i>MT2a</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen3-FK	<i>Apsy2a</i> <i>LYCB</i>	<i>MT2a</i> <i>MT2a</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen3-JFK	<i>DXS</i> <i>APsy2A</i> <i>LYCB</i>	<i>MT2a</i> <i>MT2a</i> <i>MT2a</i>	<i>Nos</i> <i>Nos</i> <i>Nos</i>		30	30
pGen2-L	<i>APsy2A</i>	<i>ACO</i>	<i>Nos</i>		30	30
pGen2-M	<i>Psy1Q60</i>	<i>ACO</i>	<i>Nos</i>		30	30
pGen2-OL	<i>APsy2a</i> <i>Crtl</i>	<i>ACO</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>	Rbcs-CTP <sup>4</sup>	30	30
pGen2-OM	<i>Psy1Q60</i> <i>Crtl</i>	<i>ACO</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>	Rbcs-CTP <sup>4</sup>	30	30
pGen4-PC	<i>Ferritin</i> <i>NAS</i>	<i>Exp1</i> <i>Ubi</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen4-QC	<i>Ferritin</i> <i>NAS</i>	<i>Exp1</i> <i>Exp1</i>	<i>Nos</i> <i>Nos</i>		30	30
pGen4-RC	<i>Ferritin</i> <i>FEA1</i>	<i>Exp1</i> <i>Ubi</i>	<i>Nos</i> <i>Nos</i>		30	30

<sup>1</sup> The *Ubi* promoter is derived from *Zea mays* (maize); others are derived from *Musa acuminata* (banana). Additionally the 35S promoter (Tobacco Mosaic Virus) and the *Nos* promoter (*Agrobacterium tumefaciens*) have been used for expression of the *npII* gene (antibiotic resistance)

<sup>2</sup> The *Nos* terminator is derived from *Agrobacterium tumefaciens* and also has been used for expression of the *npII* gene. The 35S terminator from Tobacco Mosaic Virus also has been used for the same purpose.

<sup>3</sup> The CMSSP signal peptide sequence is derived from *Chrysanthemum morifolium* (Chrysanthemum)

<sup>4</sup> The Rbcs-CTP signal peptide sequence is derived from *Pisum sativum* (Pea)

<sup>5</sup> The *Cat* intron is derived from *Ricinus communis* (Castor bean)