



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 076/2007

Licence holder: Queensland University of Technology

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

Issued: 24 April 2008
Varied: 11 December 2008
Varied: 11 May 2009
Varied: 25 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 found in a separate document entitled 'DIR 076/2007 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/dir076-2007>>.

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.

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

- (a) in relation to a Place specified in this licence as requiring Cleaning, the Destruction of the GMOs and Plant Material in that Place, to the reasonable satisfaction of the Regulator; 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.

'Deal With' in relation to a GMO means one or more of the following, as applicable:

- (a) conduct experiments with the GMO;
- (b) make, develop, produce or manufacture the GMO;

- (c) breed the GMO;
- (d) propagate the GMO;
- (e) use the GMO in the course of manufacture of a thing that is not a GMO;
- (f) grow, raise or culture the GMO;
- (g) transport the GMO;
- (h) dispose of the GMO;

and includes the possession, supply or use, of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (h)

'Decomposition Container(s)' means one or more lockable, commercial waste bins at the Field Location clearly and visibly labelled as containing GM Plant Material.

'Destroy', (or **'Destroyed'** or **'Destruction'**) means, as the case requires, killed by one or a combination of the following methods:

- (a) cutting down;
- (b) uprooting;
- (c) burning/incineration;
- (d) treatment with herbicide, or organic solvent capable of killing meristematic tissue;
- (e) decomposition, either on the ground or in a Decomposition Container(s);
- (f) autoclaving;
- (g) shredding.

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, in the case of killing the remains of harvest of the GMOs, treatment of post harvest remains by herbicide would not be a sufficient mechanism.

'Equipment' includes, but is not limited to, harvesters, storage equipment, transport equipment (eg bags, containers, trucks), materials used in cultivation practices (e.g. Bunch Covers), clothing and tools.

'Experiment(s)' means a scientific test or trial done for the purpose of testing hypotheses, gaining scientific or technical knowledge or gaining data for regulatory purposes and encompasses the process of analysis and the temporary storage of Plant Material required for experiment.

'Field Location' means an uncovered area of ground where the GMOs or other plants are planted and grown.

'Final Harvest' means, in the case of the Field Location, the removal of the last bunch(es) of fruit from the Field Location.

means, in the case of the Shadehouse, the removal of the last GMO required for the trial.

'GM' means genetically modified.

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

‘Harvest’ (or **‘Harvested’**) means the removal of fruit bunches from plants at the Field Location but does not include the Final Harvest.

‘Location’ means both the Field Location and the Shade house.

‘Natural Waterways’ means waterways other than irrigation channels, holding dams or storage ponds used to collect water runoff from irrigated areas.

‘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.

‘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.

‘Place’ means an area required to be cleaned and/or inspected under this licence in respect of each Location.

‘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’ (or **‘Ratooned’**) 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.

‘Related Species’ means plants other than Banana in the genus *Musa*.

‘Shade house’ means a lockable, glass-panelled, permanent structure located approximately 200 m from the Field Location, which is used for the purpose of hardening off GMOs before they are transferred to the Field Location.

‘Sign-off’ means a notice in writing from the Regulator, in respect of a Site, that post harvest inspection conditions no longer apply in respect of that Site.

‘Site’ means the aggregate of all Places at an address.

‘Sucker’ means a shoot arising from the roots or the base of GM or non-GM Banana plants used to propagate new plants.

‘Volunteer Plants’ means progeny of the GMOs or non-GM Banana plants grown at the Location, plants derived asexually from GM or non-GM Banana plants, or re-growth of previous GM or non-GM Banana plants.

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 Queensland University of Technology

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. In the case of transport of Plant Material, paragraph (a) of condition 10 will be satisfied by compliance with the labelling requirements of condition 49 of this licence.

12. Condition 50 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:
 - a. has been informed by the licence holder of the condition and, when applicable, its variation; and

- b. 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 written request, with copies of the signed and dated statements referred to in the immediately preceding condition.

15. 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

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.

Licence holder must provide information on matters related to suitability

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.

Additional information to be given to the Regulator

18. 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.*

19. 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

20. 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.

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

Remaining an Accredited organisation

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

Notices

23. 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

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

Permitted dealings

25. The permitted dealings are to plant, grow, propagate, harvest, transport and dispose of the GMOs, to conduct experiments with the GMOs, and to possess, supply and use the GMOs for the purpose of, or in the course of, any of the permitted dealings.

Non-GM Plants

26. Non-GM Banana may be planted and grown at the Locations, but if planted, must be handled and controlled as if it were the GMO.

27. Plant Material from non-GM Banana grown at a Location must be handled and controlled as if it were Plant Material from the GMO.

Locations, growing season and size of trial

28. With respect to the permitted dealings described in condition 25, planting, growing, propagating and harvesting must only be undertaken between May 2008 and May 2012 inclusive within the Queensland local government area of Cassowary Coast.

29. Planting and growing of the GMO must occur in either the Field Location or the Shade house such that the maximum combined area must not exceed 1.4 ha.

30. Prior to the first planting at the Field Location, the licence holder must provide a notice in writing to the Regulator of the details of the Field Location including the size, and a street address and GPS coordinates for the Site.

Notice of intention to plant and of planting

31. The licence holder must, in the manner required by condition 81, give advance notice to the Regulator of an intention to plant the GMOs.

32. The licence holder must, in the manner required by condition 82, give notice to the Regulator of the actual date of planting the GMOs.

Control measures – planting and growing

33. Fruit bunches must be covered with Bunch Covers when the young fruit begins to curve upwards. The Bunch Covers, while remaining open at the bottom, must extend below the fruit so as to discourage access to the fruit by frugivores.

34. During fruiting there must be weekly checks of the ground below the plants for fallen fruit and any fallen fruit must be placed in a Decomposition Container(s).

35. Male/hermaphrodite flowers required for Experiment must be bagged as soon as the bracts enclosing the flowers have fallen off so as to prevent:

- (a) access of nectar-feeding animals and insects; and
- (b) dispersal of pollen into the environment.

36. Male/hermaphrodite flowers not required for Experiment must be removed from the inflorescences before the bracts, which enclose the male/hermaphrodite flowers, have opened and must be Destroyed by decomposition in a Decomposition Container(s) or shredding. Once Destroyed, the remains must be placed on the ground at the Field Location.

37. All fruit not required for Experiment must be Harvested from the plants, prior to maturation, and destroyed by decomposition in a Decomposition Container(s) or shredding. Once Destroyed, the remains must be placed on the ground at the Field Location.

38. Each Decomposition Container 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.

39. 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

Experiment and storage

40. Experiment with Plant Material is only permitted if

- a. the Experiment is a notifiable low risk dealing AND

- b. the Experiment 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.*

- 41. Any Plant Material may be collected from the Location for the purpose of conducting Experiments on it or any other Dealing permitted by this licence.
- 42. Suckers may be collected from the Location for use under another DIR licence.
- 43. Any Plant Material that is collected for Experiment may be transported off the Site for the purpose of conducting Experiments on it.
- 44. Experiments must be conducted in
 - (a) a facility certified by the Regulator to 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 and stored in any one or more of these facilities.

- 45. Plant Material or waste derived from Experiments must be Destroyed as soon as practicable.

Plant Material not to be used in food

- 46. 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, Disposal and Cleaning

Transportation of Plant Material

- 47. 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 physical containment level 2 (PC2) facility or to another trial site within South Johnstone Research Station, Department of Employment, Economic Development and Innovation, Queensland (SJRS) approved by the Regulator or relocate it to the Site from a facility approved by the Regulator or from a PC2 facility.
- 48. Unless transported in accordance with conditions 49 and 50, or 51, 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.

49. GM banana Plant Material to be transported outside SJRS under condition 50 must be Packaged so as to prevent any dispersal of the GM Plant Material 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 076/2007 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 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.

50. Packaged GM banana Plant Material may be transported outside SJRS 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.

51. Transportation of GMOs and Plant Material within the Site or to another trial site within SJRS approved by the Regulator 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.

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

Disposal of Plant Material waste other than fruit and flowers

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

54. 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.

55. 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 their transfer to the ground at the Field Location.

56. 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.

Notice of Final Harvest and cleaning following Final Harvest

57. The licence holder must, in the manner required by condition 83 provide the Regulator with a notice of intention to Final Harvest the GMOs.

58. The licence holder must, in the manner required by condition 84, provide the actual date or dates of Final Harvest of the GMOs.

Harvest and post-Final Harvest procedures

59. Any fruit Harvested or Final Harvested at the Field Location must be kept separate from fruit removed from any other crop.

60. Plants may be Ratooned following Harvest

61. Fruit may be Harvested from a Plant Crop and a Ratoon crop

62. No Ratoon crops are permitted after Final Harvest.

63. If Destruction of the GMOs occurs other than in the course of the intended dealings, the GMOs are taken to have been Final Harvested for the purposes of this licence and all conditions applying to post-Final Harvest apply equally to post-Destruction.

Cleaning of Equipment and Places

64. Cleaning of Equipment must occur immediately or as soon as practicable after use and before it is used for any other purpose.

65. The following Places must be Cleaned:

- (a) the Field Location; and
- (b) the Shadehouse; and
- (c) any areas used during Harvest or Final Harvest; and
- (d) any areas used to Clean Equipment used in connection with the GMOs or Plant Material or used to Destroy the GMOs or Plant Material.

66. Each Place in respect of each Location must be Cleaned within fourteen (14) days of Final Harvest or Destruction.

67. The Licence holder must, in a manner required by condition 85 give notice to the Regulator of the date on which Cleaning of the Place concluded.

Section 6 Inspection, Use of Site and Sign-off

68. Inspections must be performed by a person who is able to recognise Volunteer Plants and Related Species.

General conditions on use of Location post - Final Harvest

69. No plants may be grown in the Field Location following its Cleaning unless the Regulator has issued a Sign-off for the Site or unless the plants are plants agreed to in writing by the Regulator.

Post - Final Harvest (or post-Destruction) Inspections at the Field Location

70. Following Cleaning, all Places Cleaned in relation to the Field Location must be inspected for the existence of Volunteer Plants and/or related species.

71. Any Volunteer Plants or Related Species identified must be Destroyed prior to the plants flowering.

72. For the Field Location, all Places required to be inspected must be inspected at least once every thirty-five (35) days, commencing on the last day of Cleaning of the Field Location and continuing until the Regulator has issued a Sign-off for the relevant Site.

73. The licence holder must, in the manner required by condition 87, record the results of inspection activities and forward the results to the Regulator.

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

Note: The Regulator will not approve the growing of Related Species prior to Sign-off.

Sign-off

75. For the Site,

- (a) if inspections have been routinely completed for a period of at least twelve (12) months; and
- (b) if inspection records for that Site show that no Volunteers have been observed in the most recent 6 month inspection period,

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

76. 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;
- (e) A description of the licence holder's plans for post-Final Harvest use of a Site during the life of this licence.

77. 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

78. 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.

79. 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.

80. 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

81. At least seven (7) days prior to the date on which planting of the GMOs is intended to commence at a Location, 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 Banana at a Location is intended to commence;
- (c) details of the Location where the GMOs will be planted;
- (d) the identity of the GMOs which are intended to be planted;

82. Within seven (7) days of planting of the GMOs at a Location 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 Banana at a Location occurred;
- (c) details of the Location where the GMOs were planted
- (d) the identity of the GMOs which were planted;

Notice of Final Harvest and Cleaning following Final Harvest

83. The licence holder must provide the Regulator with a notice of intention to Final Harvest the GMOs at the Field Location. This notice must be provided at least seven (7) days, and not more than twenty one (21) days, in advance of the intended date of Final Harvest set out in the notice. Any change of intention prior to the intended Final Harvest date must be notified to the Regulator as soon as is reasonably and practicably possible.

84. The licence holder must provide the actual date or dates of commencement of Final Harvest of the GMOs at the Field Location. This notice must be provided within seven (7) days of commencement of Final Harvest of the GMOs at the Field Location.

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

86. 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

87. 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 current land use (eg type of crop being grown) and of recent land management practices (eg irrigation, cultivation or spraying) applied in the areas inspected;
- (c) details of the date of inspection;
- (d) 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 Related Species;
- (e) the means of inspection used;
- (f) the number of Volunteer Plants or Related Species observed, if any;
- (g) details of the development stages reached by the Volunteer Plants or Related Species, if any;
- (h) details of methods used to Destroy Volunteer Plants or Related Species, if any.

88. The licence holder must keep records of the number and type of GM Banana plants grown at the Site as part of the trial, and the number of Banana plants and Plant Material from the Site stored, at the end of the trial, if any.

Transportation of Plant Material

89. 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

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

Testing methodology

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 issuing of this licence.

DIR No: 076/2007

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

Organisation Details

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Project Supervisor Details

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Organisation: Queensland University of Technology (Gardens Point Campus)

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IBC Details

IBC Name: QUT Institutional Biosafety Committee

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

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

Common Name: Banana
 Scientific Name: *Musa acuminata* cv. Williams and
Musa paradisiaca cv. Lady Finger

***Modified trait(s):**

Category: Enhancement of nutrient levels
 Description: Banana plants have been genetically modified to show increased levels of pro-vitamin A carotenoid, vitamin E or iron. Other lines contain a marker gene to allow investigation of the level of activity of a number of different promoters. All lines also contain a selective marker gene to identify transformed plant tissue.

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

Increased level of pro-vitamin A carotenoid	<i>APsy2a</i> gene from Fe'i banana <i>PsyB73</i> gene from Maize (<i>Zea mays</i>) <i>CrtI</i> gene from <i>Erwinia uredovora</i>
Increased level of vitamin E	<i>vte1</i> gene from <i>Arabidopsis thaliana</i> <i>vte2.1</i> gene from Maize (<i>Zea mays</i>) <i>vte3</i> gene from <i>Arabidopsis thaliana</i> <i>vte4</i> gene from <i>Arabidopsis thaliana</i> <i>HGGT</i> gene from Rice (<i>Oryza sativa</i>)
Increased level of iron	<i>Ferritin</i> gene from <i>Glycine soja</i> <i>IRT1</i> gene from <i>Arabidopsis thaliana</i> <i>FRO2</i> gene from <i>Arabidopsis thaliana</i>
Selectable and visual markers	<i>nptII</i> gene from <i>Escherichia coli</i> <i>uidA</i> gene from <i>Escherichia coli</i>

Purpose of the Dealings with the GMOs:

QUT applied for a licence to release up to 1,290 genetically modified (GM) banana lines into the environment on a limited scale and under controlled conditions. The purpose of the proposed trial is to conduct proof of concept research involving experiments with the GM banana lines to assess growth, fruit and yield characteristics and analyse the nutrient content of fruit and vegetative parts. A number of promoters are also being tested in order to identify those that achieve best expression of the introduced genes in the fruit. The GM bananas will not be used for human food or animal feed.