Australian Government
Department of Health
Office of the Gene Technology Regulator

Licence for dealings involving an intentional release of a GMO into the environment

Licence No.: DIR 146

Licence holder: Queensland University of Technology

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

Issued: 13 December 2016
Varied: 2 November 2018
Varied: 28 November 2019

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 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 activities involving 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 and the Department of Agriculture. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

Dealings permitted by this licence may also be subject to the operation of State legislation recognising areas as designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes.

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 A of this licence.

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.

Section 1 *Interpretations and definitions*

1. In this licence:

   (a) unless defined otherwise, words and phrases used have the same meaning as they do in the Act and the Gene Technology Regulations 2001;

   (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' 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 a Planting Area, the Destruction of the GMOs in that area, to the reasonable satisfaction of the Regulator; or

   (b) in relation to Equipment, Shadehouse and Tissue Culture Facility, the removal and/or Destruction of the GMOs, to the reasonable satisfaction of the Regulator.

'Contingency Plan' means a written plan detailing measures to be taken in the event of the unintended presence of the GMOs outside an area that must be inspected. A Contingency Plan must include procedures to:

   (a) ensure the Regulator is notified immediately if the licence holder becomes aware of the event; and

   (b) recover and/or Destroy the GMOs; and

   (c) inspect for and Destroy any Volunteers that may exist as a result of the event.

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

'Destroy', (or **'Destroyed'** or **'Destruction')** 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) discing; or

   (d) burning/incineration; or

(e) treatment with herbicide; or

(f) treatment with organic solvent capable of killing meristematic tissue; or

(g) decomposition, either on the ground or in a Decomposition Container; or

(h) shredding; or

(i) autoclaving; or

(j) in the case of a Facility, removal of the GMOs; or

(k) 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 the pseudostem is unlikely to be sufficient to kill the remaining corm and an additional destruction method 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.

'Facility' means Shadehouse, Tissue Culture Facility, or other facility approved in writing by the Regulator.

'**GM**' means genetically modified.

'**GMOs**' means the genetically modified organisms that are the subject of the dealings authorised by this licence. GMOs include live plants, suckers and pieces of the corm that are able to grow into live plants, and viable seed.

'Isolation Zone' means an area of land extending at least 10 metres in all directions from the outer edge of the Planting Area where no bananas may be grown.

'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 about an identified individual, or an individual who is reasonably identifiable:

(a) whether the information is true or not; and

(b) whether the information is recorded in a material form or not.

'Plant Material' means any part of the GM or non-GM Banana plants, 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.

'Planting Area' means an area of land where the GM and non-GM Banana are intentionally planted and grown pursuant to this licence.

'**Regulator**' means the Gene Technology Regulator.

'Shadehouse' means a permanent structure where GM and non-GM Banana plants may be planted, propagated and grown in containers.

'**Tissue Culture Facility'** means a permanent structure where GM and non-GM Banana plants may be propagated and grown in containers.

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

'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 and obligations*

3. 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.

4. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with GMOs are authorised during any period of suspension.

5. The holder of this licence ('the licence holder') is the Queensland University of Technology (QUT).

6. The persons covered by this licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise authorised by the licence holder to undertake any activity in connection with the dealings authorised by this licence.

7. The dealings authorised by this licence are to conduct experiments with the GMOs, propagate, grow, transport, and dispose of the GMOs, and the possession, supply or use of the GMOs in the course of any of these dealings.

Obligations of the Licence Holder

8. The licence holder must notify the Regulator in writing as soon as practically possible if any of the contact details of the project supervisor change from that notified in the licence application or subsequently.

Note: please address correspondence to ogtr.applications@health.gov.au.

Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following conditions address ongoing suitability of the licence holder.

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

10. The licence holder must:

(a) inform the Regulator immediately in writing, of:

i. any relevant conviction of the licence holder occurring after the issue of this licence; and

ii. 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

iii. any event or circumstances occurring after the issue of this licence that would affect the capacity of the holder of this licence to meet the conditions in it; and

(b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested, within the stipulated timeframe.

11. The licence holder must be able to access and control the Planting Area, Isolation Zone, Facilities and areas requiring Cleaning and/or post-Cleaning inspections to the extent necessary to comply with this licence, for the duration of the life of the licence.

The following conditions seek to ensure that persons conducting the dealings are aware of the licence conditions and appropriate processes are in place to inform people of their obligations.

12. Prior to conducting any dealings with the GMOs, the licence holder must provide to the Regulator:

(a) names of all organisations and persons or functions or positions of the persons who will be covered by the licence, with a description of their responsibilities; and

Note: Examples of functions or positions are 'project supervisor', site manager', 'farm labourer' etc.

(b) detail of how the persons covered by the licence will be informed of licence conditions; and

(c) detail of how the licence holder will access and control the Planting Area, Isolation Zone, Facilities and areas requiring Cleaning and post-Cleaning inspections for the duration of the licence; and

Note: this may include a description of any contracts, agreements, or other enforceable arrangements.

(d) written methodology to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism, and to distinguish between categories of GMOs approved for release; and

(e) a Contingency Plan to respond to inadvertent presence of the GMOs outside an area that must be inspected.

13. Any changes to the information provided under the immediately preceding condition must be communicated in writing to the Regulator within 14 days of the changes occurring.

14. The licence holder must inform any person covered by this licence, to whom a particular condition of the licence applies, of the following:

(a) the particular condition (including any variations of it); and

(b) the cancellation or suspension of the licence; and

(c) the surrender of the licence.

15. The licence holder must not permit a person covered by this licence to conduct any dealing unless:

(a) the person has been informed of any applicable licence conditions, including any variation of them; 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 licence conditions including any variation of them; and

ii. has understood and agreed to be bound by the licence conditions, or variation.

16. The licence holder must:

(a) inform the persons covered by this licence that any Personal Information relevant to the administration and/or enforcement of the licence may be released to the Regulator; and

(b) provide the Regulator, if requested, with copies of the signed and dated statements referred to in the immediately preceding condition.

Provision of new information to the Regulator

Licence conditions are based on the risk assessment and risk management plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment and risk management plan is communicated to the Regulator.

17. The licence holder must inform the Regulator if the licence holder becomes aware of:

(a) 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) any contraventions of the licence by a person covered by the licence; or

(c) any unintended effects of the dealings authorised by the licence.

Note: The Act requires, for the purposes of the above condition, that:

(a) the licence holder will be taken to have become aware of additional information of a kind mentioned in paragraph 17(a) if he or she was reckless as to whether such information existed; and

(b) the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in paragraph 17(b) or 17(c) if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.

Note: Contraventions of the licence may occur through the action or inaction of a person.

18. If the licence holder is required to inform the Regulator under the immediately preceding condition, the Regulator must be informed without delay.

Note: An example of informing without delay is contact made within a day of the incident via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location if required.

19. If the licence holder informs the Regulator under the immediately preceding condition and the Regulator requests further information, such information must be provided in a manner, and within the time period, stipulated by the Regulator.

Obligations of persons covered by the licence

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

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.

Section 3 *Limits and control measures*

Limits on the release

The following licence conditions maintain the risk assessment context within which the application was assessed, by imposing limits on where and when the GMOs may be grown, and on other activities that can be undertaken.

22. The only plants that may be intentionally grown at a Planting Area are:

(a) the GMOs covered by this licence as described in Attachment A of the licence;

(b) non-GM Banana plants; and

(c) plants approved in writing by the Regulator.

23. All Banana plants grown at the Planting Area are considered GMOs for the purposes of this licence.

24. Planting, propagating and/or growing of the GMOs may only occur:

(a) within one Planting Area, one Shadehouse and one Tissue Culture Facility located on the Darwin Banana Farming Company (DBFC) property in the local government area of Litchfield Municipality, Northern Territory; and

(b) on a total maximum area of 6 ha from January 2017 to January 2024.

25. 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.

Containment measures

The following licence conditions maintain the risk assessment context within which the application was assessed by restricting spread and persistence of the GMOs.

26. The outer edge of the Planting Area and any Facility must be at least 50 m away from Waterways.

27. Any extreme weather event that is expected to affect or has already affected a Planting Area or Facility, while the GMOs are growing or while the Planting Area is subject to inspection requirements, must be notified in writing to the Regulator as soon as practically and reasonably possible.

Planting Area

28. The Planting Area must be surrounded by an Isolation Zone while the GMOs are growing in the Planting Area.

29. 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.

30. Before the bracts that enclose the male/hermaphrodite flowers have opened, the flowers must either be:

(a) bagged, so as to minimise access of nectar-feeding animals and insects; or

(b) Destroyed at the Planting Area.

Shadehouse and Tissue Culture Facility

While GMOs are present within a Facility, the Facility must be secured against public access and appropriately signed so as to indicate that GMOs are present.

31. GM Banana grown in a Facility must be:

(a) grown in containers,

(b) labelled to clearly distinguish GM from non-GM Banana, and

(c) physically separated by at least 50 cm from containers of non-GM Banana.

Note: Measures to ensure GM Banana is clearly distinguishable from non-GM Banana are to prevent accidental release of the GMO and may include colour-coding of plant pots, labels on containers or plants, and labels on benches or racks.

Experimentation and storage

32. GMOs not required for experimentation or future planting must be Destroyed as soon as practicable.

33. If experimentation with the GMOs is not conducted in accordance with Notifiable Low Risk Dealings (NLRD) requirements, such activities may only be undertaken within:

(a) the Planting Area prior to post-harvest Cleaning; or

(b) a Facility on the DBFC property; or

(c) a facility approved in writing by the Regulator.

Note: Dealings conducted in accordance with NLRD requirements must be assessed by an IBC before commencement, must comply with the requirements of the Gene Technology Regulations 2001, and are not subject to the conditions of this licence.

34. If GMOs are stored prior to experimentation, they must be stored in a Facility within an unbreakable container labelled as containing GMOs or Destroyed as soon as practicable after use

Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 47).

Cleaning

35. The Planting Area and Facilities must be Cleaned once the GMOs are no longer intended to be grown at the area.

36. If all the GMOs have been Destroyed in the Planting Area, then the area is taken to have been Cleaned for the purposes of this licence and all post-Cleaning conditions would apply.

While post-Cleaning inspection requirements apply to the Planting Area:

(a) the area must be maintained in a manner appropriate to allow identification of Volunteers; and

(b) no plants may be planted in the Planting Area following its Cleaning unless the plants are:

i. the GMOs or non-GM Banana planted in accordance with the conditions of this licence; or
ii. agreed to in writing by the Regulator.

37. For a Facility, once Cleaning has been completed, the licence holder must send a notification to the Regulator that the Facility has been Cleaned.

38. Cleaning of Equipment must occur as soon as practicable after use and before use for any other purpose.

39. In the case of Equipment used at a Planting Area, the Equipment must be cleaned before it is removed from the area.

Transportation

40. If transport or storage is not conducted in accordance with NLRD requirements, it must be conducted in accordance with conditions 41 and 42.

Note: Dealings conducted in accordance with NLRD requirements must be assessed by an IBC before commencement, must comply with the requirements of the Gene Technology Regulations 2001 and are not subject to conditions of this licence.

41. Transport and storage of GMOs to and from the DBFC property must:

(a) only occur to the extent necessary to conduct the dealings permitted by this licence or other valid authorisations by the Regulator; and

(b) be in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* for PC2 GM plants as current at the time of transportation or storage; and

(c) comply with all other conditions of this licence.

Note: Condition 15 requires signed statements for persons transporting or disposing of the GMOs.

42. Transport within the DBFC property 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.

43. Methods and procedures used to transport GMOs must be recorded, and must be provided to the Regulator, if requested.

Disposal of the GMOs and Plant Material

44. If a Decomposition Container is used, it must be:

(a) located within a Facility and/or Planting Area, and

(b) appropriately signed to indicate that GMOs are present , and

(c) its contents only be accessible to persons covered by the licence.

Persistence of the GMOs post-Cleaning

45. Post-Cleaning areas of land must be inspected by people trained to recognise Banana. Inspections must cover the entirety of areas to be inspected. Actions must be taken as follows:

Area of land	Period of inspection	Inspection frequency	Inspect for	Action
Planting Area	From the day of completion of Cleaning of the Planting Area, until: i. the area is replanted with the GMO; or ii. the Regulator has issued a Sign-off for the area.	At least once every 90 days	Volunteers	Destroy within 7 days

46. Details of any inspection activity must be recorded in a Logbook and must include:

(a) date of the inspections;

(b) name of the person(s) conducting the inspections;

(c) details of the experience, training or qualification that enables the person(s) to recognise Volunteers, if not already recorded in the logbook;

(d) details of areas inspected including current land use (including details of any post-harvest crops), and recent management practices applied (eg irrigation or cultivation);

Note: this may also include spraying or maintenance measures used to facilitate inspections for Volunteers

(e) details of any post-Cleaning Volunteers observed including number, developmental stage and approximate position of the Volunteers within each area inspected;

(f) date(s) and method(s) of Destruction of any Volunteers.

Note: Details of Inspection activities must be provided to the Regulator (Condition 0).

Contingency plan

47. If any unintentional presence of the GMOs is detected outside the areas requiring inspection, the Contingency Plan must be implemented.

Section 4 *Sign off*

48. The licence holder may make written application to the Regulator that planting restrictions and inspection requirements no longer apply to the Planting Area if:

(a) all post-Cleaning inspection activities have been conducted for at least 12 months on the area; and

(b) no Volunteers have been detected on this area in the most recent six month inspection period.

The Regulator will take into account the management and inspection history for the area, including post-harvest crops planted (if any) and application of herbicide or other management of any occurrence of Volunteers, in deciding whether or not further inspections are required to manage persistence of the GMOs.

Section 5 *Reporting and Documentation*

The following licence conditions are imposed to demonstrate compliance with other conditions, facilitate monitoring of compliance by staff of the OGTR, and emphasise appropriate selection of the Planting Area.

49. Notifications must be sent to the Regulator as follows:

Notice	Content of notice	Timeframe
(a) Intention to transport GMOs to and from a Facility at the DBFC property	i. Identity of the Facility which will contain the GMOs ii. Details of the Facility including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the site (e.g. Google maps) and any other descriptions, if not previously provided iii. Identity of the GMOs to be transported (e.g. lines or construct details) and where they originated iv. Date on which the GMOs will be transported v. Expected date of removal of GMOs from the Facility and their destination.	At least 7 days prior to each transport of GMOs to a Facility (to be updated immediately if the notified details change)
(b) Transporting GMOs to a Facility	i. Actual date(s) of transporting the GMOs ii. Any changes to the details provided under part (a) of this condition.	Within 7 days of any transporting of GMOs to a Facility
(c) Intention to Plant at the Planting Area	i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the site (e.g. Google maps) and any other descriptions, if not previously provided ii. Identity of the GMOs to be planted (e.g. lines or construct details) and where they originated iii. Date on which the GMOs will be planted iv. If GMOs have previously been planted at the Planting Area, a history indicating how the Planting Area has been used in the preceding 2 years, including details of previous GMOs and post-harvest crops planted v. How the Planting Area is intended to be used during the first year following Cleaning.	At least 7 days prior to each planting (to be updated immediately if the notified details change)
(d) Planting at the Planting Area	i. Actual date(s) of planting the GMOs at the Planting Area ii. Any changes to the details provided under part (c) of this condition.	Within 7 days of any planting
(e) Cleaning of Planting Area and Facilities	i. Date(s) on which any areas needing Cleaning were Cleaned ii. The area Cleaned, and iii. Method of Cleaning.	Within 7 days of completion of any Cleaning
(f) Inspection activities	i. Information recorded in a Logbook as per the inspection requirements (Conditions 45 and 46).	Within 35 days of Inspection

Note: Other reports and documents that may need to be sent to the Regulator are described under Conditions 10(a), 10(b) and 17.

ATTACHMENT A

DIR No: 146

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)
GPO Box 2434
BRISBANE QLD 4001

Phone No: (07) 3138 1326

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 Cavendish, Williams, Grande Naine, Gros Michel Dwarf Cavendish*

M. accuminata x M. balbisiana cv Lady Finger

Modified traits:

Categories: Disease resistance
Antibiotic resistance

Description: Banana plants have been genetically modified for disease resistance by *Agrobacterium*-mediated transformation. Each line contains one of the candidate genes for disease resistance described in Table 1, and may also contain the antibiotic resistance marker gene *nptII* described in Table 2. The regulatory sequences are detailed in Table 3 of this attachment.

Purpose of the dealings with the GMOs:

Queensland University of Technology has applied for a licence to release lines of genetically modified (GM) banana into the environment on a limited scale and under controlled conditions. The purpose of the release is to evaluate the level of disease resistance and agronomic performance of the GM banana plants under field conditions. The GM banana is not permitted to be used for human food or animal feed.

Commercial confidential information (CCI)

Some details of the genes and genetic elements inserted into the GM banana lines were declared CCI under Section 185 of the *Gene Technology Act 2000*.

Table 1. The candidate genes introduced into the GM banana lines

Gene name	Gene – full name & description	Accession number/ genome identifier	Intended Function
R1	*CCI*	*CCI*	Fusarium resistance
R2	*CCI*	*CCI*	Fusarium resistance
R3	*CCI*	*CCI*	Fusarium resistance
R4	*CCI*	*CCI*	Fusarium resistance
R5	*CCI*	*CCI*	Fusarium resistance
R6	*CCI*	*CCI*	Fusarium resistance
R7	*CCI*	*CCI*	Fusarium resistance
AA1	*CCI*	*CCI*	Enhanced stress tolerance & inhibition of apoptosis
RGA2	*850-RGA2 - Banana nucleotide binding site-leucine rich repeat (NBS-LRR) type resistance gene*	*EU616673*	Fusarium resistance
Ced-9	*Cell death abnormality gene-9*	*AAA20080*	Inhibition of apoptosis
R8	*CCI*	*CCI*	Fusarium resistance
R9	*CCI*	*CCI*	Fusarium resistance
R10	*CCI*	*CCI*	Fusarium resistance
R11	*CCI*	*CCI*	Fusarium resistance
R12	*CCI*	*CCI*	Fusarium resistance
R13	*CCI*	*CCI*	Fusarium resistance
R14	*CCI*	*CCI*	Fusarium resistance
R15	*CCI*	*CCI*	Fusarium resistance

Table 2. The selectable marker gene introduced into the GM banana lines

Gene name	Gene – full name & description	Accession number/ genome identifier	Intended Function
nptII	*Neomycin phosphotransferase type II gene*	*M61162*	Selectable marker – antibiotic resistance

Table 3. Regulatory genetic elements introduced into the GM banana lines

Genetic element	Function in GM plant	Source
pNos	Promoter from the nopaline synthase (*nos*) gene	*A. tumefaciens*
tNos	Termination and polyadenylation signal from the *nos* gene	*A. tumefaciens*
pR1	Promoter region from the banana R1 gene	banana (*CCI*)
tR1	Termination and polyadenylation signal from the banana R1 gene	banana (*CCI*)
pR2	Promoter region from the banana R2 gene	banana (*CCI*)
tR2	Termination and polyadenylation signal from the banana R2 gene	banana (*CCI*)
pR3	Promoter region from the banana R3 gene	banana (*CCI*)
tR3	Termination and polyadenylation signal from the banana R3 gene	banana (*CCI*)
pR4	Promoter region from the banana R4 gene	banana (*CCI*)
tR4	Termination and polyadenylation signal from the banana R4 gene	banana (*CCI*)
pR5	Promoter region from the banana R5 gene	banana (*CCI*)
tR5	Termination and polyadenylation signal from the banana R5 gene	banana (*CCI*)
pR6	Promoter region from the banana R6 gene	banana (*CCI*)
tR6	Termination and polyadenylation signal from the banana R6 gene	banana (*CCI*)
pR7	Promoter region from the banana R1 gene	banana (*CCI*)
tR7	Termination and polyadenylation signal from the banana R1 gene	banana (*CCI*)
pRGA2	Promoter from the RGA2 gene (*NBS-LRR type resistance gene)*	banana (*CCI*)
tRGA2	Termination and polyadenylation signal from the RGA2 gene *(NBS-LRR type resistance gene)*	banana (*CCI*)
Ma-pTIP2	Root specific promoter	*M. acuminate* ssp. *malaccensis*
pUbi	Promoter region from the *ubiquitin* gene	maize
Ubi intron	Intron from *ubiquitin* gene used to enhance protein translation	maize
TEV	Leader sequence to enhance protein translation	TEV
Ma-pAct	Promoter region from the *actin* gene	Musa spp. cv Bluggoe
Ma-Act intron	Intron from *actin* gene used to enhance gene expression	Musa spp. cv Bluggoe
Ma-tAct	Termination and polyadenylation signal from the *actin* gene	Musa spp. cv Bluggoe
p35S	Promoter from 35S RNA	CaMV
t35S	Termination and polyadenylation signal from 35S RNA	CaMV
pLacZ	Promoter from LacZα	*E. coli*
pR8	Promoter region from the banana R8 gene	banana (*CCI*)
tR8	Termination and polyadenylation signal from the banana R8 gene	banana (*CCI*)
pR9	Promoter region from the banana R9 gene	banana (*CCI*)
tR9	Termination and polyadenylation signal from the banana R9 gene	banana (*CCI*)
pR10	Promoter region from the banana R10 gene	banana (*CCI*)
tR10	Termination and polyadenylation signal from the banana R10 gene	banana (*CCI*)
pR11	Promoter region from the banana R11 gene	banana (*CCI*)
tR11	Termination and polyadenylation signal from the banana R11 gene	banana (*CCI*)
pR12	Promoter region from the banana R12 gene	banana (*CCI*)
tR12	Termination and polyadenylation signal from the banana R12 gene	banana (*CCI*)
pR13	Promoter region from the banana R13 gene	banana (*CCI*)
tR13	Termination and polyadenylation signal from the banana R13 gene	banana (*CCI*)
pR14	Promoter region from the banana R14 gene	banana (*CCI*)
tR14	Termination and polyadenylation signal from the banana R14 gene	banana (*CCI*)
pR15	Promoter region from the banana R15 gene	banana (*CCI*)
tR15	Termination and polyadenylation signal from the banana R15 gene	banana (*CCI*)

ATTACHMENT B

Checklist of documents that must be sent to the Regulator:

When	What	Condition	Timeframe
Prior to conducting any dealings	Details of persons covered	12(a)	
	Plan to inform people covered by the licence	12(b)	
	Plan to ensure control and access to the Site	12(c)	
	Detection methodology	12(d)	
	Contingency plan	12(e)	
Prior to planting	Intention to transport GMOs to or from a Facility	49(a)	At least 7 days prior to any transporting of GMOs
	Transporting GMOs to a Facility	49(b)	Within 7 days of any transporting of GMOs
	Intention to Plant at the Planting Area	49(c)	At least 7 days prior to each planting
Planting	Planting at the Planting Area	49(d)	Within 7 days of any planting
Post-Cleaning	Cleaning	49(e)	Within 7 days of completion
	Inspection	49(f)	Within 35 days of each inspection
Any time after issue of the licence	Any changes of the project supervisor contact details	8	As soon as practicable
	Any relevant conviction, revocation, suspension or cancellation of any relevant permit or circumstances that may affect compliance to licence conditions	10(a)	Immediately, if occurs
	Any information relevant to on-going suitability	10(b)	If and when requested
	Any changes to details provided under conditions 12(a) - 12(e)	13	Within 14 days of the changes
	Signed statements from persons covered under the licence	16(b)	If and when requested
	Any additional information regarding health and safety of the people and the environment, contraventions of this licence or any unintended effects of the dealings authorized by the licence	17	As soon as practically and reasonably possible, after becoming aware
	Extreme weather conditions	27	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport	43	If and when requested