



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 078/2007

Licence holder: The University of Queensland

Title: Limited and controlled release of sugarcane genetically modified for altered sugar production

Issued: 29 August 2008

Varied: 21 January 2009

Varied: 13 March 2009

Varied: 8 October 2009

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the licence. This document can be obtained from the Office of the Gene Technology Regulator website at <http://www.ogtr.gov.au>, or by telephoning the Office on 1800 181 030.

Gene Technology Regulation in Australia

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form a substantial part of a nationally consistent regulatory system controlling the development and use of genetically modified organisms (GMOs).

This licence is issued by the Gene Technology Regulator in accordance with the *Gene Technology Act 2000* and, as applicable, Corresponding State Law.

The Gene Technology Regulator is required to consult with, and take into account advice from a range of key stakeholders, including other regulatory authorities, on risks to human health and safety and to the environment in assessing applications for dealings involving the intentional release of GMOs into the Australian environment.

Other agencies that also regulate GMOs or GM products include Food Standards Australia New Zealand, Australian Pesticide and Veterinary Medicine 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 078/2007 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/dir078-2007>

Licence conditions

Section 1 Interpretations and Definitions

1. This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

2. In this licence:

- (a) unless defined otherwise in this licence, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;
- (b) words importing a gender include any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing persons include a partnership and a body whether corporate or otherwise;
- (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;
- (f) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;
- (g) specific conditions prevail over standard conditions to the extent of any inconsistency.

3. In this licence:

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

'Annual Report' means a written report provided to the Regulator within ninety (90) days of each anniversary of issue of this licence containing all the information required by this licence to be provided in the Annual Report.

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

- (a) in relation to 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.

'Crossing Facility' means a facility where GM sugarcane may be crossed with other non-GM sugarcane plants under controlled conditions.

‘Crush’ (or **‘Crushed’** or **‘Crushing’**) means processing of harvested Sugarcane to extract Sugarcane juice.

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

- (a) uprooting by ploughing;
- (b) rotary hoeing;
- (c) mulching by machinery;
- (d) treatment with herbicide;
- (e) slashing;
- (f) crushing;
- (g) burning;
- (h) autoclaving

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 breeding practices (e.g. pollen lanterns), clothing and tools.

‘Field Location’ means an uncovered area of ground where the GMOs or other plants are planted and grown, but does not include the Guard Row or Isolation Zone.

‘Final Harvest’ means the removal of the last GMO required for the trial at a Location.

‘GM’ means genetically modified.

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

‘Guard Rows’ means at least 2 rows of non-GM Sugarcane located not more than 3m from, and entirely surrounding, a Field Location and grown in such a way as to reasonably promote growth commensurate with the growth of the GMOs.

‘Guard Row Plant’ means non-GM Sugarcane.

‘Harvest’ (or **‘Harvested’**) means the removal of GMOs or GM plant material at the Field Location but does not include the Final Harvest.

‘Headland’ means an area of land at least 4 metres wide, surrounding the location, that is free of sugarcane.

'Isolation Zone' means an area of land extending at least 3 metres in all directions from the outer edge of a Field Location.

'Location' means a Field Location, a Nursery, or a Crossing Facility where the GMOs or other plants may be intentionally grown pursuant to this licence, but does not include the Isolation Zone.

'Natural Waterways' means waterways other than irrigation channels, holding dams or storage ponds used to collect water runoff from irrigated areas but which excludes Lilliesmere lagoon.

'Nursery' means a Location where GM and/or non-GM sugarcane may be grown outdoors in pots from tissue culture, stem cuttings or seed.

'OGTR' means the Office of the Gene Technology Regulator.

'Personal Information' means information or an opinion (including information forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

'Place' means an area with respect to Location required to be Cleaned and/or inspected under this licence.

'Plant Material' means any part of the GM or non-GM Sugarcane plants grown at a Location, whether viable or not, including, but not limited to, 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 stem is cut down and a new stem is permitted to grow from the base of the plant.

'Related Species' means plants other than Sugarcane in the genus *Saccharum*.

'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 required to be Cleaned for a Location, including the Location and equipment cleaning areas.

'Sugarcane' means commercial cultivars of sugarcane.

'Trial Locality' means a Trial Locality identified in Table 1.

'Volunteer Plants' means progeny of the GMOs or non-GM Sugarcane plants grown at the Location, plants derived asexually from GM or non-GM Sugarcane plants (setts), or regrowth of previous GM or non-GM Sugarcane plants that have not been intentionally grown.

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 The University of Queensland.

Project Supervisor

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

7. The licence holder must immediately notify the Regulator in writing if any of the contact details of the Project Supervisor change.

No dealings with the GMOs except as authorised by this licence

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

Persons covered by this GMO licence

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

Informing people of their obligations

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

- (a) the particular condition (including any variations of it);
- (b) the cancellation or suspension of the licence;
- (c) the surrender of the licence.

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

- (a) the person has been informed of the condition, including any variation of it, and
- (b) the licence holder has obtained from the person a signed and dated statement that the person,
 - i. has been informed by the licence holder of the condition and, when applicable, its variation and

- ii. has understood and agreed to be bound by the condition, or its variation, and
- iii. has not conducted the dealing without being informed of the condition, or its variation.

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

13. The licence holder must notify the project supervisor and all persons covered by a licence that Personal Information collected by the licence holder which is relevant to the administration and/or enforcement of the licence may be released to the Regulator.

Applicant to notify of circumstances that might affect suitability

14. The licence holder must immediately, by notice in writing, inform the Regulator of:

- (a) any relevant conviction of the licence holder occurring after the commencement of this licence; and
- (b) any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment; and
- (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it.

Licence holder must provide information on matters related to suitability

15. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

Additional information to be given to the Regulator

16. It is a condition of this licence that the licence holder informs the Regulator if the licence holder:

- (a) becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or
- (b) becomes aware of any contraventions of the licence by a person covered by the licence; or
- (c) becomes aware of any unintended effects of the dealings authorised by the licence.

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

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

- (b) *the licence holder will be taken to have become aware of contraventions, or unintended effects, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

17. The licence holder must provide the information required by paragraphs (a), (b) and (c) of the immediately preceding condition to the Regulator as soon as practically and reasonably possible, and must also include the information in the Annual Report.

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

18. If a person is authorised by this licence to Deal with the GMOs and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

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

Remaining an Accredited organisation

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

Notices

21. The licence holder must provide all notices to the Regulator required to be given by this licence and each notice must be provided in the manner required by Section 6 of this licence.

Section 3 Growing the GMOs

GMOs covered by this licence

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

23. This licence allows dealings with the GMOs at Location(s) which are currently subject to the conditions of licence DIR 051/2004 even if Sign-off has not occurred with respect to that Location. To the extent that any condition under DIR 051/2004 is inconsistent with the conditions applying under this licence with respect to Dealings conducted,

(a) at the Location of DIR 051/2004, and/or

(b) the Site in respect of that Location,

the conditions of this licence prevail.

Permitted dealings

24. The permitted dealings are to plant, grow, propagate, harvest, transport and dispose 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

25. Non-GM Sugarcane may be planted and grown at the Field Locations, but if planted, must be handled and controlled as if it were the GMO.
26. Plant Material from non-GM Sugarcane grown at a Field Location must be handled and controlled as if it were Plant Material from the GMO.
27. At the Nursery and Crossing Facilities non-GM sugarcane plants may be grown at the same Location.
28. If non-GM plants which are grown at a Nursery or Crossing Facility are crossed with GM sugarcane then the Plant Material must be handled and controlled as if it were Plant Material from the GMO.

Locations, growing season and size of trial

29. With respect to the permitted dealings described in condition 24, planting, growing, propagating, harvesting and final harvesting must only be undertaken between September 2008 and December 2014.
30. Planting may only take place within a Trial Locality indicated in Table 1 below.
31. No more than fifteen Locations may be used for the planting and growing of the GMO.
32. The maximum combined area of all Locations must not exceed 65 ha over the 6 year period described in condition 29.
33. A Location within a Trial Locality must not exceed the size indicated in Table 1.

Table 1: Total area (ha) for the permitted dealings at the fifteen Locations in the six local government areas (LGA).

| LGA | Trial Locality | Number of Locations | Size (ha) |
|--------------|-------------------------------|---------------------|-----------------------------|
| Burdekin | Kalamia (Nursery) | 1 | 0.25 |
| | Kalamia (Field Location) | 1 | 12.3 |
| | Burdekin (Field Locations) | 5 | 30 (6 ha per Location) |
| | Kalamia (Field Location) | 1 | 20 |
| Mackay | Mackay (Field Location) | 1 | 0.66 |
| Moreton Bay | Woodford (Field Location) | 1 | 0.66 |
| Bundaberg | Bundaberg (Field Locations) | 2 | 0.72 (0.36 ha per Location) |
| | Bundaberg (Crossing Facility) | 1 | 0.01 |
| Cairns | Meringa (Crossing Facility) | 1 | 0.01 |
| Hinchinbrook | Macknade (Crossing Facility) | 1 | 0.001 (10m ²) |

34. Only GM single eye setts, tissue-culture derived GM plants and/or GM seed may be planted at a Nursery and all plantings must take place in pots.
35. Crossing of GM sugarcane lines with non-GM sugarcane plants may only be undertaken at the Nursery or Crossing Facilities described in Table 1.

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

Notice of intention to plant and of planting

37. The licence holder must, in the manner required by condition 79, give advance notice to the Regulator of an intention to plant the GMOs.

38. The licence holder must, in the manner required by condition 80, give notice to the Regulator of the actual date of planting the GMOs.

Control measures – planting and growing

39. Sites must be located on land that is not subject to flooding and located at least 50 metres away from the nearest natural waterway.

40. Any Field Location growing GM sugarcane must be separated from any adjacent commercially grown sugarcane by Guard Rows and Headlands.

41. Each Field Location must be surrounded by Guard Rows and/or an Isolation Zone.

42. No crops, including sugarcane may be planted in the Isolation Zone.

43. Any Field Location growing GM sugarcane must be separated from any accessible public area by a Guard Row.

44. Guard Rows, Isolation Zones and Headlands must be able to be accessed and controlled by the licence holder to an extent that is commensurate with the licence holder's rights to access and control the Location within them.

45. GM sugarcane plants at a Nursery or Crossing Facilities must be clearly identifiable eg by physical separation or labelling.

46. In the event that weather conditions prevent burning of the GM sugarcane on completion of the trial, the piled up billets (small sections of sugarcane) must be surrounded by a star picket fence with chicken wire to 1 metre and an electric fence strand until weather conditions allow final destruction of the GM sugarcane.

Monitoring for the initiation of flowering of the GMOs at the Crossing Facilities, and prevention of pollen transfer

47. The licence holder must monitor every 4 days during the likely flowering period for the emergence of flower panicles on any of the GMOs grown in the Crossing Facilities.

48. The licence holder must prevent unintentional pollen transfer from the GMOs by:

- (a) covering inflorescences with a pollen lantern; or
- (b) removing the inflorescence

49. The licence holder must report initiation of flowering in writing to the Regulator, within 7 days of its being observed at the Crossing Facilities.

Section 4 Use of Plant Material

Experiment and storage

50. 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.*

51. Any Plant Material may be collected from a Location for the purpose of conducting experiments on it or any other Dealing permitted by this licence.

52. Any Plant Material that is collected for experiment may be transported off the Site to:
- (a) a facility certified by the Regulator to Physical Containment level 2 facility (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/or analysed and Destroyed as soon as practicable or stored in any one or more of these facilities.

Plant Material not to be used in food

53. The GMOs and Plant Material including juice 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

54. Plant Material may only be transported for the purposes of, or in the course of a permitted dealing.

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

Notice of Final Harvest and cleaning following Final Harvest

56. The licence holder must, in the manner required by condition 81 provide the Regulator with a notice of intention to Final Harvest the GMOs.

57. The licence holder must, in the manner required by condition 82, provide the actual date or dates of Final Harvest of the GMOs.

Harvest and Final Harvest procedures

58. Any GMO Harvested at a Location must be kept separate from any other sugarcane plants.

59. GM sugarcane plants may be ratooned following Harvest but not following Final Harvest.

Cleaning of Equipment and Places

60. In the case of Equipment used at the Site, the Equipment must be cleaned before it is removed from the Site (eg if a mechanical harvester is used at a Site it must be Cleaned before it is moved to another Site).

61. The following Places must be Cleaned:

- (a) the Location;
- (b) Guard Rows and/or Isolation Zone;
- (c) any areas used during Harvest and Final Harvest;
- (d) any areas used to process or Crush Plant Material; and
- (e) any areas used to Clean Equipment used in connection with the GMOs or Plant Material or used to Destroy the GMOs or Plant Material.

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

63. The Licence holder must, in a manner required by condition 83 give notice to the Regulator of the date on which Cleaning of the Place concluded.

Section 6 Inspection, Use of Site and Sign-off

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

65. If GMOs are grown at the Kalamia Trial Locality adjacent to Lilliesmere lagoon, the western side of Lilliesmere lagoon must be inspected at least once every 6 months until Final Harvest for the presence of Volunteers and any Volunteers identified must be destroyed within one (1) week of being detected.

General conditions on use of Location on completion of the trial

66. No plants may be grown in a 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-Destruction Inspections at the Field Location Site

67. Following Cleaning, Field Location Sites, and the western side of Lilliesmere lagoon must be inspected for the existence of Volunteer Plants and/or Related Species.

68. Any Volunteer Plants or Related Species identified must be Destroyed within one (1) week of being detected.

69. Field Location Sites and the western side of Lilliesmere lagoon must be inspected at least once every thirty-five (35) days, commencing on the last day of Cleaning of the Site and continuing until the Regulator has issued a Sign-off for the relevant Site.

70. The licence holder must, in the manner required by condition 85, record the results of inspection activities and forward the results to the Regulator.

71. 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

72. For a Field Location Site,

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

the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site.

73. For Nurseries and Crossing facilities, once Cleaning has been completed for an associated Site, 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

74. 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-harvest use of a Site during the life of this licence.

75. 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

76. 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.

77. 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.

78. 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

79. At least seven (7) days prior to the date on which the first planting of the GMOs at a Location is intended to commence, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) date on which planting of the GMOs is intended to commence;
- (b) the date on which planting of any non-GM Sugarcane 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;

80. Within fourteen (14) 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 Sugarcane occurred at a Location
- (c) details of the Location where the GMOs were planted, including the size of the Location, a street address and GPS coordinates for the Location;
- (d) the identity of the GMOs which were planted; if GMOs have previously been planted at a Field Location a history indicating how the Field Location has been used in the preceding two years, including details of previous GMOs and post-harvest crops planted at the Field Location.
- (e) the period during which the licence holder considers the GMOs are likely to flower;
- (f) the period during which the licence holder considers the GMOs are likely to be Final Harvested;
- (g) the period during which the licence holder considers the GMOs are likely to be Destroyed;
- (h) a description of how the Location is intended to be used during the first two years following Final Harvest of the GMOs.

Notice of Final Harvest and Cleaning following Final Harvest

81. The licence holder must provide the Regulator with a notice of intention to Final Harvest the GMOs at a 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.

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

83. The licence holder must provide a notice in writing to the Regulator when a Site 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.

84. 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

85. 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.

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

Transportation of Plant Material

87. 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

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

Testing methodology

89. 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: 078/2007

***Full Title:** Limited and controlled release of sugarcane genetically modified for altered sugar production

Organisation Details

Organisation: The University of Queensland

Postal address: *[Information Redacted]*

Phone No: *[Information Redacted]*

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: The University of Queensland

Postal Address: *[Information Redacted]*

IBC Details

IBC Name: The University of Queensland

Table 1 Genetic elements which may be used in combination with the genes conferring the modified traits.

| Genetic Element | Type of regulatory element | Source |
|---|------------------------------|--|
| <i>ubi</i> (<i>pubi 1</i>) | Promoter | <i>Zea mays</i> |
| <i>emu</i> | Promoter | Artificial construct |
| <i>Banana Streak Virus (CV)</i> | Promoter | Banana Streak Virus |
| <i>P67(P67B)</i> | Promoter | <i>Saccharum</i> spp. |
| <i>H07, Myb, Lsg</i> | Promoter | <i>Saccharum</i> spp. |
| <i>Rubisco SS(rbcS)</i> | Promoter | <i>Oryza sativa</i> |
| <i>PEP carboxylase (SCV4)</i> | Promoter | <i>Sorghum</i> |
| <i>Shrunken (sh1)</i> | Promoter | <i>Zea mays</i> |
| <i>BBTV (BBTV 6.1)</i> | Promoter | Banana Bunchy Top Virus |
| <i>RoIC</i> | Promoter | <i>Agrobacterium tumefaciens</i> |
| <i>Ocs and Nos</i> | Terminator | <i>A. tumefaciens</i> |
| <i>H07 and Myb</i> | Terminator | <i>Saccharum</i> spp. |
| <i>Actin, rubisco, ubiquitin, glutelin</i> genes | Terminator | <i>O. sativa</i> |
| Introns from sugar metabolism genes | Intron | <i>O. sativa, Sorghum, Saccharum</i> spp., |
| Introns from sugarcane genes | Intron | <i>Saccharum</i> spp., |
| <i>CTTP (+/-ERc)</i> | Signal peptide | <i>Nicotiana tabacum</i> |
| <i>NTTP (+/-ERc)</i> | Signal peptide | <i>Ipomoea batatas</i> |
| <i>HDEL/KDEL</i> | Signal peptide | ubiquitous |
| <i>Tonoplast intrinsic protein domain (α-TIP)</i> | Protein stabilising sequence | <i>Phaseolus vulgaris</i> |
| <i>Tonoplast intrinsic protein domain (γ-TIP)</i> | Protein stabilising sequence | <i>Z. mays</i> |
| <i>BP-80 vacuole targeting domain</i> | Protein stabilising sequence | <i>Pisum sativum</i> |
| Six his tag | - | synthetic |