



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 095

Licence holder: BSES Limited

Title: Limited and controlled release of sugarcane genetically modified for altered plant growth, enhanced drought tolerance, enhanced nitrogen use efficiency, altered sucrose accumulation, and improved cellulosic ethanol production from sugarcane biomass

Issued: 24 July 2009

Varied: 18 December 2009

Varied: 14 May 2010

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 095 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/dir095>.

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 Sugarcane plants (non-GM or specified GMOs grown under this licence) under controlled conditions in accordance with the conditions of this licence.

'Crush' (or **'Crushing'**) means processing of Sugarcane to extract Sugarcane juice.

'Destroy', (or **'Destroyed'** or **'Destruction'**) means, as the case requires, killed by one or more 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;
- (i) hand weeding, or
- (j) a method approved in writing by the Regulator.

Note: 'As the case requires' has the effect that depending on the circumstances, one or more of these techniques may not be appropriate. For example, used individually, treatment by uprooting by ploughing or slashing would not be sufficient mechanisms to kill the plant material and would require an additional treatment such as herbicide or burning, respectively.

'Equipment' includes, but is not limited to, harvesters, storage equipment, transport equipment (eg bags, containers, pots, trucks), materials used in breeding practices (eg pollen lanterns), Sugarcane Crushing machinery, clothing and tools.

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

'Final Harvest' means a Harvest following which the GMOs are not intended to be Ratooned at a Location.

'Flowering' is taken to begin when any plant of the class of plants referred to in a particular condition first flowers, and is taken to end when all plants in the class of plants no longer have flowers.

'GM' means genetically modified.

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

'Guard Row' means at least one (1) row of non-GM Sugarcane located not more than three (3) metres 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.

'Harvest' (or **'Harvested'**) means the removal of the GMOs or GM Plant Material at the Location but does not include the removal of small samples.

'Isolation Zone' means an area of land extending at least six (6) metres in all directions from the outer edge of the Guard Row surrounding a Field Location, in which no crops may be cultivated and growth of Related Species must be controlled.

'Juice Laboratory' means a building in which Sugarcane is Destroyed by Crushing, and juice extracted.

'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.

'Logbook' means a written or electronic record kept at a central location within each of the BSES stations, containing information required to be collected and maintained by this licence and which is able to be presented to the OGTR on request.

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

'Nursery' means a Location where GM and/or non-GM Sugarcane may be grown outdoors in pots.

'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.

'Plant Material' means any part of the GM or non-GM Sugarcane plants grown at a Location or Guard Row, whether viable or not, including, but not limited to, seed, pollen, stems, stem sections, plant bases and leaves, whether from the plant itself or produced by the plant.

'Ratoon' (or **'Ratooned'**) means the process whereby, following Harvest of stem material, plants are permitted to re-grow from the remaining base of the plant.

'Regulations' means the *Gene Technology Regulations 2001*

'Regulator' means the Gene Technology Regulator.

'Related Species' means plants other than Sugarcane in the genus *Saccharum* and plants of the genera *Miscanthus*, *Erianthus* and *Imperata*.

'Sign-off' means a notice in writing from the Regulator, in respect of a Place, that post Cleaning conditions no longer apply in respect of that Place.

'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 derived from hybridisation of *Saccharum officinarum* and *Saccharum spontaneum*.

'Volunteer Plants' means 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 BSES Limited.

Project Supervisor

6. The Project Supervisor in respect of this licence is the 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.

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

- (a) a list of the names of all organisations or natural persons who will be persons covered by this licence. Where a name of a person is not known at the time of submitting the list, the function or position of the person to be covered must be provided; and
- (b) a description of the responsibilities of the licence holder and of each person covered by the licence in relation to the requirements of this licence.

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

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

Informing people of their obligations

12. 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.

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

- (a) the person has been informed of the condition, including any variation of it; and
- (b) the licence holder has obtained from the person a signed and dated statement that the person:
 - i) has been informed by the licence holder of the condition and, when applicable, its variation; and
 - ii) has understood and agreed to be bound by the condition, or its variation; and
 - iii) has not conducted the dealing without being informed of the condition, or its variation.

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

15. Prior to growing the GMOs the licence holder must provide to the Regulator 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.

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

17. 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.

Licence holder to notify of circumstances that might affect suitability

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

- (a) any relevant conviction of the licence holder occurring after the commencement of this licence;
- (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;
- (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

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

Additional information to be given to the Regulator

20. 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.*

21. 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

22. 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.

23. The licence holder must be able to access and control all Sites, approved facilities or other premises to the extent necessary to comply with this licence, for the duration of the life of the licence.

24. Where the licence holder does not have legal access and control of a Site, approved facility or other premise to the extent necessary to comply with this licence, for the duration of the life of the licence, then prior to growing the GMOs, the licence holder must provide to the Regulator a description of how any contracts, agreements, or other enforceable arrangements will allow the licence holder to access and control a Site, approved facility or other premise to the extent necessary to comply with this licence, for the duration of the life of the licence.

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

Remaining an Accredited organisation

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

Notices

27. 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 7 of this licence.

Section 3 Growing the GMOs

GMOs covered by this licence

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

Permitted dealings

29. The permitted dealings with the GMOs are to plant, grow, propagate, breed, Harvest, transport and dispose of the GMOs, to conduct experiments with the GMOs, and the possession, supply and use of the GMOs for the purpose of any of the permitted dealings with the GMOs, or in the course of any of these dealings.

Non-GM Plants

30. 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 GMOs.

31. Plant Material from non-GM Sugarcane grown at a Field Location or Guard Row must be handled and controlled as if it were Plant Material from the GMOs.

32. Non-GM Sugarcane plants may be grown at the same Nursery and Crossing Facility as the GMOs.

33. If non-GM plants which are grown at a Crossing Facility are crossed with GM Sugarcane then the Plant Material of the non-GM plant must be handled and controlled as if it were Plant Material from the GMOs.

Limits - Locations, timing and size of trial

34. With respect to the permitted dealings described in condition 29, planting, growing, propagating, breeding and Harvesting must only be undertaken between August 2009 and August 2015, inclusive, within the Queensland local government areas of Moreton Bay Regional Council, Bundaberg Regional Council, Mackay Regional Council, Burdekin Shire Council and Cairns Regional Council.

35. Establishment of Field Locations, Nurseries and Crossing Facilities may only take place at BSES Limited stations as specified in Table 1. The total area of all Locations of each type at each BSES station over the duration of the permitted dealings must not exceed the

maximum size indicated in Table 1. The number of Field Locations, Nurseries and Crossing Facilities at which the GMOs are grown in any one season must not exceed the numbers indicated in Table 1.

Table 1: Types, maximum number and maximum size of Locations at BSES Limited stations at which permitted dealings may occur.

BSES station	Local government area	Address	Type of Location	Maximum no. of Locations at any one time	Maximum total size of all Locations
BSES Woodford	Moreton Bay	Lot 207, Old Cove Rd, Woodford, Qld 4514	Field Location	3	3.98 ha
			Nursery	1	200 m ²
BSES Southern	Bundaberg	Ashfield Rd, Bundaberg, Qld 4670	Field Location	10	3.974 ha
			Crossing Facility	1	60 m ²
			Nursery	1	200 m ²
BSES Central	Mackay	Peak Downs Highway, Te Kowai, Qld 4741	Field Location	10	3.98 ha
			Nursery	1	200 m ²
BSES Burdekin	Burdekin	Bruce Highway Brandon, Qld 4808	Field Location	10	3.98 ha
			Nursery	1	200 m ²
BSES Meringa	Cairns	71378 Bruce Highway, Meringa, via Cairns, Qld 4870	Crossing Facility	1	200 m ²
BSES Durrie	Burdekin	35 Sayers Road, The Durrie farm, Barratta, 4809	Field Location	10	3.98 ha
			Nursery	1	200 m ²

Control measures – planting and growing

36. All GMOs generated by *Agrobacterium*-mediated transformation must be assayed using the polymerase chain reaction (PCR) for the presence of *Agrobacterium tumefaciens* prior to their first planting at any Location, and may not be planted if *Agrobacterium tumefaciens* is detected. The results must be notified to the Regulator as required by condition 79, and the methods and procedures used for the PCR assay must be documented and provided to the Regulator on request.

37. Nurseries may only be used for the cultivation of GM Sugarcane that:

- (a) is grown in the Nursery from GM single-eye setts and/or is transported to the Nursery as tissue-culture derived GM plants and/or seedlings derived from GM seed germinated at Crossing Facilities;
- (b) is planted in pots;
- (c) is labelled as GM Sugarcane and clearly distinguishable from non-GM Sugarcane;
- (d) is kept on a separate bench to any non-GM Sugarcane, the bench being labelled to indicate it holds GM Sugarcane;
- (e) is kept on a separate bench to any GM Sugarcane released under another licence; and
- (f) is prevented from Flowering.

Note: Measures to ensure GM Sugarcane is clearly distinguishable from non-GM Sugarcane may include colour-coding of plant pots or labels on pots or plants.

38. Nurseries must be signed to indicate they contain GM Sugarcane.
39. Field Locations may be planted with GM Sugarcane originating at a Nursery or with setts Harvested from other Field Locations.
40. Only one or more of the following may be used as a Crossing Facility:
 - (a) one (1) area of a glasshouse in which the GMOs may be cultivated from setts;
 - (b) one (1) outdoor area for germinating setts on seedling benches and cultivating seedlings;
 - (c) one (1) area of a photoperiod facility (a structure equipped to modify daylength and/or temperature);
 - (d) at BSES Meringa, one (1) outdoor area for cultivation of GM Sugarcane in pots, immediately adjacent to the photoperiod facility;
 - (e) at BSES Meringa, one (1) area in a crossing shed in which cut inflorescences from the GMOs may be kept, but plants may not be grown in pots;
 - (f) one (1) box in which GM Sugarcane seed is stored, which must be clearly labelled and must be locked when unattended;
 - (g) a germination chamber in which GM Sugarcane seed may be germinated.
41. At a Crossing Facility:
 - (a) GM Sugarcane plants must be planted in pots;
 - (b) GM Sugarcane plants must be kept in areas clearly identified as containing GM Sugarcane, and these areas must be separated from non-GM Sugarcane by a distance of at least one (1) metre;
 - (c) any non-GM Sugarcane grown in an area identified as containing GM Sugarcane must be handled and controlled as if it were the GMOs;
 - (d) GM Sugarcane plants and cut GM Sugarcane inflorescences must be labelled as GM Sugarcane and be clearly distinguishable from non-GM Sugarcane;
 - (e) crossing of GM Sugarcane lines with GM or non-GM Sugarcane plants may be undertaken only with GM Sugarcane lines belonging to categories specified in Attachment B as being allowed for crossing;
 - (f) cut GM Sugarcane inflorescences must be kept in an area clearly identified as containing GM Sugarcane and separated from non-GM Sugarcane inflorescences by a distance of at least one (1) metre, except when undergoing crossing to non-GM Sugarcane as permitted by this condition;
 - (g) pollen dispersal from the GMOs must be controlled in the manner required in condition 48;

- (h) structures surrounding areas making up a Crossing Facility must be signed to indicate they contain GM Sugarcane (eg glasshouse, photoperiod facility, crossing shed).

Note: The licence holder must give notices to the Regulator in relation to intention to plant, actual date of planting, and Flowering of the GMOs as specified in Section 7 of this licence.

Note: For the purposes of this licence, planting means the commencement of cultivation of each GMO at each Field Location, Nursery and Crossing Facility, eg GMOs are considered to be planted in a Nursery when transferred there from other Locations.

Containment measures

42. With the exception of the photoperiod facility at BSES Meringa, Places must be located such that the outer edge of the Place is at least fifty (50) metres away from the nearest natural waterway.
43. Field Locations in which the GMOs are growing must be surrounded by a Guard Row and an Isolation Zone.
44. No crops may be planted in the Isolation Zone, which must be maintained in a manner that allows the identification of Sugarcane and Related Species while the GMOs are growing at the Field Location. This could be achieved by keeping the Isolation Zone free of any vegetation.
45. If any Sugarcane or Related Species occur in the Isolation Zone while the GMOs are being grown at a Location, the Sugarcane or Related Species must be Destroyed immediately.

Inspecting for initiation of Flowering of the GMOs at Crossing Facilities, and control of pollen transfer

46. The licence holder must inspect GMOs grown in Crossing Facilities for spikelet opening three times weekly during the Flowering period.
47. The findings of Crossing Facility inspection activities must be recorded in a Logbook. The information recorded must include at least the following:
- (a) details of the areas inspected;
 - (b) details of the date of inspection;
 - (c) the names of the person or persons who undertook the monitoring and details of the experience, training or qualification that enabled them to recognise spikelet opening; and
 - (d) the developmental stages reached by the GMOs, including the number of GMOs at each developmental stage.

Note: In addition to the above inspections, the licence holder must give other notices to the Regulator in relation to Flowering and crossing of the GMOs as specified in Section 7 of this licence.

48. In Crossing Facilities and in all areas of photoperiod facilities in which the GMOs are grown, unintentional pollen transfer between GMOs and between the GMOs and non-GM Sugarcane must be restricted by:

- (a) removing and Destroying Sugarcane inflorescences prior to spikelet opening; or
- (b) completely enclosing Sugarcane inflorescences with pollen-impermeable lanterns with no openings, prior to spikelet opening; or
- (c) implementing the following control measures if spikelets have opened on Sugarcane inflorescences which are not enclosed in pollen lanterns:
 - i) removing and Destroying opened spikelets as soon as practicable; and
 - ii) Destroying the inflorescences or completely enclosing the inflorescences with pollen-impermeable lanterns with no openings prior to further spikelets opening.

Note: this condition applies to the GMOs and to non-GM sugarcane grown in Crossing Facilities and also to non-GM sugarcane grown in the same photoperiod facility as the GMOs.

Section 4 Use of Plant Material

Use of Plant Material obtained from Harvest or Final Harvest

49. Plant Material obtained from Harvest or Final Harvest must be Destroyed within 14 days unless it is:

- (a) used for planting in a subsequent growing season in accordance with this licence; or
- (b) used in accordance with another relevant authorisation under the Act; or
- (c) used in the course of destructive experimental analysis; or
- (d) stored for the purposes of paragraphs (a), (b) or (c) in:
 - i. a facility certified by the Regulator as a PC2 facility; or
 - ii. a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is stored within the facility; or
- (e) stored for the purposes of Destruction in:
 - i. a plastic bag within a wheelie bin which is locked and fixed in position when unattended, and signed to indicate it contains GM Plant Material; or
 - ii. a Holding Area which is authorised under licence DIR096, provided the Plant Material originates from the same BSES research station as the authorised Holding Area;
 - iii. a Juice Laboratory located on one of the BSES Limited stations described in Table 1 which is signed so as to indicate that GM Plant Material is stored within the facility.

Note: For the immediate preceding condition, if a Holding Area authorised under licence DIR 096 is used for the storage and Destruction of Plant Material originating from this licence the Plant Material would be subject to all requirements for inspection, reporting and Sign-off of the Holding Area in accordance with licence DIR 096.

Note: This licence does not authorise any dealings in certified physical contained facilities. Such dealings may be conducted as notifiable low risk dealings, in accordance with all applicable requirements of the Gene Technology Regulations 2001. Dealings conducted with Plant Material under a notifiable low risk dealing are not subject to conditions of this licence.

Plant Material not to be used in food

50. The GMOs, Plant Material and cane juice must not be used, sold or otherwise disposed of for any purpose which would involve or result in their use as feed for animals or food for humans.

Section 5 Harvest, Transport, Cleaning and Disposal

Harvest procedures

51. Any GMO Harvested at a Location must be kept separate from any other Sugarcane plants.

52. GM Sugarcane plants may be Ratooned following Harvest until a maximum of three (3) Ratoons have been Harvested from the GMOs planted at a Location.

Note: The licence holder must give notices to the Regulator in relation to intention to Harvest or Final Harvest and actual date of Harvest or Final Harvest as specified in Section 7 of this licence.

Transportation of Plant Material

53. Plant Material may only be transported to the extent necessary to store it, Destroy it, export it, Clean it from Equipment, relocate it to another Location for planting under this licence, relocate it to a facility approved by the Regulator or to a physical containment level 2 (PC2) facility for the purposes of this licence, relocate it for dealings under another relevant authorisation under the Act, or relocate it to the Site from a facility approved by the Regulator or from a PC2 facility..

54. Unless occurring within a BSES station listed in Table 1, Plant Material must be transported in accordance with the guidelines for the transportation of GM Plant Material found in the Regulator's *Guidelines for the Transport of GMOs* as current at the time of transportation, and routes, methods and procedures used for this transportation in accordance with this licence must be documented and provided to the Regulator on request.

55. Transport of Plant Material occurring within a BSES station described in Table 1 may only be undertaken in accordance with conditions 56 to 60, as applicable, or in accordance with the Regulator's *Guidelines for the Transport of GMOs* as current at the time of transportation. If transport is undertaken according to conditions 56 to 60, the licence holder must have in place accounting procedures to ensure the same quantity of Plant Material sent is delivered, and routes, methods and procedures used for transportation must be recorded in a Logbook.

56. Transportation of GM Sugarcane stalk material within a BSES station for planting or for destructive analysis may be undertaken if:

- (a) the GM sugarcane stalk material is bundled and labelled (eg with a barcode);
- (b) the bundled material is transported in a covered trailer;
- (c) the trailer is followed and observed to ensure that no stalk material is lost during transportation;
- (d) all transported material is accounted for at the destination (eg by scanning barcode labels).

57. Transportation within a BSES station of GM Sugarcane seedlings in trays from a Nursery bench to a Field Location for planting may be undertaken if:

- (a) the trays or seedlings are labelled (eg with a barcode) and secured in a covered trailer;
- (b) the trailer is followed and observed to ensure that no material is lost during transportation;
- (c) all transported material is accounted for at the destination (eg by scanning barcode labels).

58. Transportation of GM Sugarcane inflorescences from the photoperiod facility to the crossing shed, which are both within the BSES Meringa Crossing Facility, may occur if:

- (a) inflorescences are not shedding any pollen or are completely enclosed in pollen-impermeable material to prevent pollen escape;
- (b) each inflorescence is labelled (eg with a barcode);
- (c) the transport vehicle is followed and observed to ensure no inflorescences are lost during transportation;
- (d) all transported material is accounted for at the destination (eg by scanning barcode labels).

59. Transportation of harvested Plant Material within a BSES station to an area for destruction, may be undertaken if:

- (a) Plant Material is in a truck which is covered securely (eg with a tarpaulin) so as to fully contain the material;
- (b) the truck is followed and observed to ensure that no material is lost during transportation.

60. Small amounts of Harvested Plant Material may be stored and transported to an area used to Destroy Plant Material in lockable bins (eg wheelie bins) which are labelled as containing GM Plant Material.

Note: Movement of Plant Material within areas required to be inspected and Signed off under this licence is not regarded as transportation or subject to restrictions, provided that it is carried out prior to Cleaning of those areas. For example, prior to Cleaning of a Field Site, Harvested Plant Material may be moved from the Field Location, across the associated

Guard Row and Isolation Zone to an area immediately adjacent to the Isolation Zone at which the Plant Material will be Destroyed.

Cleaning of Equipment

61. Cleaning of Equipment must occur immediately or as soon as practicable after use and before it is used for any other purpose (eg equipment used to Crush GM Sugarcane must be Cleaned before it is used to Crush other Sugarcane).

62. Equipment used at a Site 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).

Cleaning of Places

63. The following Places must be Cleaned within 14 days of their use for any of the indicated purposes:

- (a) any areas used to Clean Equipment;
- (b) any areas used to process or Crush Plant Material; or
- (c) any areas used to Destroy the GMOs or Plant Material.

64. Following Final Harvest at a Location, the following Places associated with the Location must be Cleaned within fourteen (14) days:

- (a) the Location;
- (b) Guard Row;
- (c) Isolation Zone;
- (d) any areas used to Clean Equipment;
- (e) any areas used to process or Crush Plant Material; and
- (f) any areas used to Destroy the GMOs or Plant Material

65. Each Nursery and Crossing Facility must be Cleaned as soon as practicable after use, and before being used for another purpose.

Note: Other conditions of this Licence require the Licence Holder to make records and give notices to the Regulator in relation to Cleaning of Places (Section 6 – Use of Places post Cleaning and Place Sign-Off; Section 7 – Reporting and Documentation Requirements).

Section 6 Use of Places and Place Sign-off

General conditions on use of Locations and other Places post-Cleaning

66. No plants may be grown in a Place, other than a Nursery or Crossing Facility, following its Cleaning unless:

- (a) the Regulator has issued a Sign-off for the Place; or
- (b) the plants are plants agreed to in writing by the Regulator.

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

Post-Cleaning Inspections

67. Inspections must be performed by a person who is able to recognise Volunteer Plants and Related Species.
68. Following Cleaning, all Places, except for Nurseries or Crossing Facilities, must be inspected for the existence of Volunteer Plants and Related Species.
69. All Places which must be inspected for the existence of Volunteer Plants and Related Species must be maintained in a manner appropriate to allow the identification of any Volunteer Plants and Related Species.
70. All Places which must be inspected for the existence of Volunteer Plants and Related Species must be inspected at least once every thirty-five (35) days, commencing on the last day of Cleaning of the Place and continuing until the Regulator has issued a Sign-off for the relevant Place.
71. Any Volunteer Plants and Related Species identified must be Destroyed immediately.
72. The findings of post-Cleaning inspection activities must be recorded in a Logbook. The information recorded must include 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 developmental stages reached by the Volunteer Plants or Related Species, if any; and
 - (h) details of methods used to Destroy Volunteer Plants or Related Species, if any, and the date of destruction, if different from the date of inspection.
73. Inspection requirements do not apply in respect of a Place if the licence holder has received a Sign-off for the Place.

Note: Results of inspection activities must be provided to the Regulator as required in Section 7 of this licence.

Sign-off

74. For each Place requiring post-Cleaning inspection:

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

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

Section 7 Reporting and Documentation Requirements

Contingency Plans

75. 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.

76. 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.

77. 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, of planting and Flowering

78. At least seven (7) days prior to the date on which planting of the GMOs is intended to commence, 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 Sugarcane at a Location is intended to commence;
- (c) details of the Location where the GMOs will be planted, including its size, the type of Location (eg Nursery, Crossing Facility or Field Location), a street address and GPS coordinates for the Location;
- (d) the category of the GMOs which are intended to be planted;
- (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 Harvested;
- (g) for Field Locations, the number of Ratoons for which the licence holder considers it likely the GMOs will be cultivated and Harvested;

- (h) the period(s) during which the licence holder considers the GMOs are likely to be Destroyed;
- (i) if GMOs have previously been planted at a Field Location, a history indicating details of previous GMOs and post-Harvest crops planted at the Location and how the Location has been used in the preceding two years; and
- (j) for Field Locations, a description of how the Location is intended to be used during the first twelve (12) months following Final Harvest of the GMOs.

Note: For the purposes of this licence, planting means the commencement of cultivation of each GMO at each Field Location, Nursery and Crossing Facility, eg GMOs are considered to be planted in a Nursery when transferred there from other Locations.

79. Within seven (7) days of planting of the GMOs, 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 its size, the type of Location (eg Nursery, Crossing Facility or Field Location), a street address and GPS coordinates for the Location;
- (d) the category of the GMOs which were planted;
- (e) for the first planting of any GMOs generated by *Agrobacterium*-mediated transformation, the results of PCR tests for the presence of *Agrobacterium* in each GMO;
- (f) information to identify the Location or PC2 facility where the GMOs previously were before planting;
- (g) if GMOs have previously been planted at a Field Location, a history indicating details of previous GMOs and post-Harvest crops planted at the Location and how the Location has been used in the preceding two years;
- (h) the period during which the licence holder considers the GMOs are likely to flower;
- (i) the period during which the licence holder considers the GMOs are likely to be Harvested;
- (j) for Field Locations, the number of Ratoons for which the licence holder considers it likely the GMOs will be cultivated and Harvested;
- (k) the period(s) during which the licence holder considers the GMOs are likely to be Destroyed;
- (l) for Field Locations, a description of how the Location is intended to be used during the first twelve (12) months following Final Harvest of the GMOs.

80. Within seven (7) days of the commencement of Flowering of the GMOs at any Field Location or Crossing Facility within each BSES station each season, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the actual date on which Flowering of the GMOs commenced;
- (b) the period during which the licence holder considers the GMOs likely to remaining Flowering;
- (c) for a Crossing Facility:
 - i. the period during which crosses are expected to be undertaken;
 - ii. measures to be taken to control pollen dispersal;
 - iii. crosses expected to be undertaken;
- (d) the period during which the licence holder considers the GMOs are likely to be Harvested; and
- (e) the period(s) during which the licence holder considers the GMOs are likely to be Destroyed.

81. Within seven (7) days of commencement of crossing with the GMOs at a Crossing Facility, the licence holder must provide a notice in writing to the Regulator.

82. Where the crosses undertaken vary from those expected to be undertaken, as notified to the Regulator under condition 80(c)iii, the actual crosses undertaken must be notified in writing to the Regulator.

Notice of Harvest or Final Harvest and Cleaning following Final Harvest

83. The licence holder must provide the Regulator with a notice of intention of Harvest or 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 Harvest or Final Harvest set out in the notice. Any change of intention prior to the intended date must be notified to the Regulator as soon as is reasonably and practically possible. In the notice the licence holder must specify if there is intention to Ratoon the GMOs following Harvest of a Field Location.

84. The licence holder must provide a notice in writing to the Regulator with the actual date or dates of Harvesting and Final Harvesting of the GMOs at a Location. This notice must be provided within seven (7) days of commencement of Harvesting of the GMOs. The notice must specify if GMOs Harvested from a Field Location will be Ratooned.

85. The licence holder must provide a notice in writing to the Regulator when a Place, except for a Nursery or Crossing Facility, is Cleaned. The notice must be provided to the Regulator within fourteen (14) days of the date on which Cleaning of the Place 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.

Notice of inspection activities

87. The findings of post Cleaning inspections, as recorded in the Logbook, 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.

Other records to be kept

88. The licence holder must keep records of the Cleaning of Nurseries or Crossing Facilities, in a Logbook, and provide the information in the record to the Regulator upon request.

89. The licence holder must keep records of the number and category of GM Sugarcane lines grown at each Location as part of the trial, and of the number of GM Sugarcane plants and Plant Material from the Locations stored at the end of the trial, if any, in a Logbook, and provide the information in the record to the Regulator upon request.

Annual Report

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

Note: Conditions 21 and 87 specify information that must be included in an Annual Report.

Testing methodology

91. 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 detection method should be capable of reliably distinguishing between GMOs described in this licence and those described in other licences. The instrument must be provided within 30 days of the issuing of this licence.

DIR No: 095

***Full Title:** Limited and controlled release of sugarcane genetically modified for altered plant growth, enhanced drought tolerance, enhanced nitrogen use efficiency, altered sucrose accumulation, and improved cellulosic ethanol production from sugarcane biomass

Organisation Details

Postal address: * BSES Limited
50 Meiers Rd
Indooroopilly
QLD 4068

Phone No: 07 3331 3333

Project Supervisor Details

Surname: *[Personal Information Redacted]*

First Name: *[Personal Information Redacted]*

Title: *[Personal Information Redacted]*

Phone No: *[Personal Information Redacted]*

Fax: *[Personal Information Redacted]*

Email Address: *[Personal Information Redacted]*

Position: *[Personal Information Redacted]*

Organisation: *[Personal Information Redacted]*

Postal Address: * 50 Meiers Rd
Indooroopilly
QLD 4068

IBC Details

IBC Name: BSES Limited IBC

GMO Description

The GMOs covered by this licence:

Saccharum spp. genetically modified by introduction of only the genes, promoters and terminators described below.

*Parent Organism:

Common Name: Sugarcane
 Scientific Names: *Saccharum* spp. hybrid

*Modified traits:

Categories: Altered plant growth
 Improved drought tolerance
 Improved nitrogen use efficiency
 Enhanced sucrose accumulation
 Enhanced cellulosic ethanol production from sugarcane biomass
 Antibiotic resistance
 Marker gene expression

Description: Sugarcane plants have been genetically modified for altered plant growth, improved drought tolerance, improved nitrogen use efficiency, enhanced sucrose accumulation and enhanced cellulosic ethanol production from sugarcane biomass. The lines contain one antibiotic resistance marker and may include a second antibiotic resistance marker. One category also includes a marker gene. Up to 500 lines from each of the categories described in Table 1 of this attachment may be released.

Purpose of the dealings with the GMOs:

BSES Limited has applied for a licence to release up to 12, 500 genetically modified sugarcane lines into the environment on a limited scale and under controlled conditions. The purpose of the release is to assess the agronomic potential of the GM sugarcane lines, and the extent to which they may contribute to increasing sugarcane yield and the sustainability of sugarcane production by more efficient use of resources. Some of the GM sugarcane lines may be crossed to each other or to non-GM sugarcane.

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

Refer to Tables 1 and 2 of this attachment.

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

Table 1: Genes responsible for conferring the modified traits.

GMO group	Category	May be crossed? ¹	Gene(s) ²	Source organism	Genbank Accession	Construct function	Promoter ³	Terminator ³	Targeting sequence ³
Marker gene expression	1	Yes	<i>nptII</i>	<i>Escherichia coli</i>	AF234316.1	Expression	<i>Ubi1</i>	<i>nos</i>	none
Marker and reporter gene expression	2	No	<i>nptII + uidA</i>	<i>Escherichia coli</i>	AF234316.1 AY292368	Expression	<i>Ubi1</i>	<i>nos</i>	none
Altered plant growth	3	No	<i>PcGA2ox-1</i>	<i>Phaseolus coccineus</i>	AJ132438	Expression	Any	<i>nos</i>	none
	4	Yes	<i>HvGA20ox-1</i>	<i>Hordeum vulgare</i>	AY551428	Expression	Any	<i>nos</i>	none
	5	Yes	<i>HvGA20ox-2</i>	<i>Hordeum vulgare</i>	n/a	Expression	Any	<i>nos</i>	none
	6	No	<i>OstB1</i>	<i>Oryza sativa</i>	AB088343	Expression	Any	<i>nos</i>	none
	7	No	<i>ShTB1</i>	<i>Saccharum</i> spp. (sugarcane)	n/a	Expression	Any	<i>nos</i>	none
	8	No	<i>ShTB1</i>	<i>Saccharum</i> spp. (sugarcane)	n/a	RNAi	Any	<i>nos</i>	none
Enhanced drought tolerance	9	Yes	[this is confidential commercial information]			Expression	Any	<i>nos</i>	Any or none
	10	Yes	[this is confidential commercial information]			Expression	Any	<i>nos</i>	None
	11	Yes	<i>OsDREB1A</i>	<i>Oryza sativa</i>	AF300970	Expression	Any	<i>nos</i>	None
Enhanced nitrogen assimilation	12	No	<i>ZmDof1</i>	<i>Zea mays</i>	D78377	Expression	Any	<i>nos</i>	None
Enhanced sucrose accumulation	13	No	[this is confidential commercial information]			RNAi	<i>Ubi1</i>	Any	None
	14	No	[this is confidential commercial information]			RNAi	<i>Ubi1</i>	Any	None
	15 ⁴								
	16 ⁴								
	17 ⁴								
	18	No	[this is confidential commercial information]			RNAi	<i>Ubi1</i>	Any	None
	19 ⁴								
Enhanced cellulosic ethanol production from	20	No	[this is confidential commercial information]			RNAi	<i>Ubi1</i>	<i>nos</i>	None
	21	No	[this is confidential commercial information]			Expression	Any	<i>nos</i>	Any or none
	22	No	[this is confidential commercial information]			Expression	Any	<i>nos</i>	Any or none

GMO group	Category	May be crossed? ¹	Gene(s) ²	Source organism	Genbank Accession	Construct function	Promoter ³	Terminator ³	Targeting sequence ³
sugarcane biomass	23	No	<i>[this is confidential commercial information]</i>			Expression	Any	<i>nos</i>	Any or none
	24	No	<i>[this is confidential commercial information]</i>			Expression	Any	<i>nos</i>	Any or none
	25	No	<i>[this is confidential commercial information]</i>			Expression and RNAi	Any	<i>nos</i>	Any or none

¹ Indicated categories may be crossed to other GM sugarcane categories or to non-GM sugarcane.

² All categories may contain *neomycin phosphotransferaseII* from *E. coli* and *β-lactamase* from *E. coli*.

³ "Any" promoter, terminator or targeting sequence refers to any sequence listed in table 2 of this attachment as performing that function.

⁴ Categories 15, 16, 17 and 19, as assessed in the RARMP for DIR 095, may not be released.

Table 2: Regulatory sequences which may be combined with the genes responsible for conferring the modified traits, as described in Table 2.

Function	Regulatory Sequence	Genbank Accession	Source
Promoter	<i>Ubi1 (Ubiquitin1)</i>	S94464	<i>Zea mays</i> (maize)
	<i>[this is confidential commercial information]</i>		<i>Hordeum vulgare</i> (barley)
	<i>[this is confidential commercial information]</i>		<i>Sorghum bicolor</i> (sorghum)
	<i>[this is confidential commercial information]</i>		<i>Arabidopsis thaliana</i>
	<i>[this is confidential commercial information]</i>		<i>Arabidopsis thaliana</i>
Targeting sequence	Legumain targeting domain	DQ458784	<i>Saccharum</i> spp. (sugarcane)
	Rubisco small subunit targeting domain	X04334	<i>Pisum sativum</i> (pea)
Terminator	<i>nos (nopaline synthase)</i>	V00087	<i>Agrobacterium tumefaciens</i>
	<i>ocs (octopine synthase)</i>	X00493	<i>Agrobacterium tumefaciens</i>
	<i>tml (tumour morphology large)</i>	X00493	<i>Agrobacterium tumefaciens</i>