



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 129

Licence holder: Sugar Research Australia Ltd

Title: Limited and controlled release of sugarcane genetically modified for herbicide tolerance

Issued: 24 October 2014

Varied: 05 November 2015

Varied: 20 November 2015

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 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 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 declaring areas to be GM, GM free, or both, 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* (Commonwealth) or the corresponding State legislation under which this licence is issued.

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

- (a) in relation to an area specified in this licence as requiring Cleaning, the Destruction of the GMOs and Plant Material in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs and Plant Material from the Equipment, 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 or Plant Material 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 Destroy any of the GMOs or Plant Material; and
- (c) inspect for and Destroy any Volunteers that may exist as a result of the event.

‘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;
- (b) rotary hoeing;
- (c) mulching by machinery;

- (d) treatment with herbicide from chemical groups other than those to which the GM sugarcane is tolerant;
- (e) slashing;
- (f) crushing;
- (g) burning/incineration;
- (h) autoclaving;
- (i) hand weeding;
- (j) storing in a secure container (i) until decomposed to the satisfaction of the Regulator or (ii) emptying the contents of the container onto an area requiring Cleaning, post-Harvest inspections and Sign-off; 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 individually the treatment of post-Harvest remains by herbicide may not be a sufficient mechanism.

'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.

'Facility' means Nursery, Crossing Facility, Hot water treatment facility, Juice Laboratory or other facility approved in writing by the Regulator.

'Final Harvest' means Harvest following which the GMOs are not to be Ratooned.

'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 that are the subject of the dealings authorised by this licence.

'Guard Row' means at least one (1) row of non-GM Sugarcane entirely surrounding a Planting Area of GM sugarcane, 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.

'Holding Area' means a dedicated area within a SRA station where Plant Material is stored and then Destroyed.

'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 Planting Area.

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

'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 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 an area at an SRA station where GM and/or non-GM Sugarcane may be handled, prepared for planting or grown (but not in the ground).

‘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.

‘Planting Area’ means an area of land where the GMOs are intentionally planted and grown pursuant to this licence.

‘Plant Material’ means any part of the GM or non-GM Sugarcane plants grown under this licence, whether viable or not, including, but not limited to, seed, pollen and material cut from plants as part of standard cultural practice, whether from the plant itself or derived from or produced by the plant, but not including cane juice extracted from stem material by Crushing or material made non-viable for experimental analysis.

‘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.

‘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 an area, that post-harvest obligations no longer apply in respect of that area.

‘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 planted.

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 Sugar Research Australia Limited (SRA).
6. The licence holder must notify the Regulator as soon as practically possible if any of the contact details of the project supervisor change.

Note: please address correspondence to the Director, Monitoring Section of the OGTR.

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

Obligations of the Licence Holder

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 commencement 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 commencement 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 all Planting Areas, Guard Rows, Isolation Zones, and Facilities 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 'Site manager', 'Farm labourer', 'Courier' 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 all Planting Areas, Guard Rows, Isolation Zones and Facilities 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, the genetic modifications and distinguish between categories of the GMOs of this licence and other licences; 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, via OGTR.M&C@health.gov.au.

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 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) 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. For example if it is a condition of the licence that volunteers are destroyed prior to reaching maturity and a volunteer reaches maturity, then the person responsible for controlling volunteers will have contravened that licence condition.

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 at the time 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, the further 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 planted and grown in a Planting Area and Facility are:

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

- (b) plants approved in writing by the Regulator; and
- (c) non-GM sugarcane plants.

23. Planting and growing of the GMOs may only occur within the following limits:

SRA station	Local government area	Type of location	Maximum size of area	Duration
SRA Southern	Bundaberg Regional Council	Planting Area	8 ha	October 2015 – November 2021, inclusive
		Nursery	3600 m ²	
ISIS Central Sugar Mill Co. Ltd	Bundaberg Regional Council	Planting Area	8 ha	October 2015 – November 2021, inclusive
SRA Central	Mackay Regional Council	Planting Area	8 ha	October 2015 – November 2021, inclusive
		Nursery	1600 m ²	
SRA Burdekin	Burdekin Shire Council	Planting Area	8 ha	October 2015 – November 2021, inclusive
		Nursery	4000 m ²	
SRA Durre	Burdekin Shire Council	Planting Area	8 ha	October 2015 – November 2021, inclusive
SRA Herbert	Hinchinbrook City Council	Planting Area	6 ha	October 2015 – November 2021, inclusive
		Nursery	2000 m ²	
SRA Meringa	Cairns City Council	Nursery	200 m ²	October 2015 – November 2021, inclusive
		Crossing Facility	200 m ²	
SRA Woodford	Moreton Bay Regional Council	Planting Area	8 ha	October 2015 – November 2021, inclusive
		Nursery	3300 m ²	

23A To the extent that dealings with any of the GMOs described in Attachment A are subject to a condition of DIR 096 that is inconsistent with a condition of this licence, the condition of this licence prevails, except that conditions 75 to 83 of DIR 096 continue to apply where replanting of a Location described in Table 1 of DIR 096 has not commenced pursuant to this licence.

Note: Effectively, DIR 096 post-cleaning monitoring obligations (including with respect to Holding Areas) continue until either Sign-off has been issued under DIR 096 or replanting of a DIR 096 site occurs under this licence.

24. Plant Material and cane juice extracted from the GMOs 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.

25. Plant Material from non-GM Sugarcane grown at a Planting Area or in a Guard Row must be handled and controlled as if it were Plant Material from the GMOs.

26. If non-GM plants 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.

27. If any unintentional presence of the GMOs or Plant Material from the GMOs is detected outside the areas requiring cleaning and inspection, the Contingency Plan must be implemented.

Control measures during growing, raising, culturing, breeding and propagating the GMOs

The following licence conditions restrict the spread and persistence of the GMOs or Plant Materials from the GMOs beyond the limits imposed on the trial and during other activities.

28. All Facilities must be signed to indicate they contain GM Sugarcane.

29. Planting Areas, Nurseries and the Crossing Facility, with the exception of the photoperiod Facility (a part of Crossing Facility at Meringa), must be located such that the outer edge of the area is at least 50 metres away from the nearest Natural Waterway.

Nurseries

30. Nurseries may only be used for

- (a) preparation of GM sugarcane for planting (eg transfer from plates, hot water treatment, cutting setts); or
- (b) cultivation of GM Sugarcane that:
 - i. is planted in plates, pots or trays;
 - ii. is labelled to clearly distinguish GM from non-GM Sugarcane;
 - iii. is kept on a separate bench to any non-GM Sugarcane, the bench being labelled to indicate it holds GM Sugarcane;
 - iv. is kept on a separate bench to any GM Sugarcane released under another licence; and
 - v. is prevented from Flowering.

Note: Measures to ensure GM Sugarcane is clearly distinguishable from non-GM Sugarcane may include colour-coding/labelling of pots or trays.

Crossing Facility

31. Breeding with the GMOs is only permitted at the Crossing Facility at SRA Meringa station. The Crossing Facility may consist of one or more of the following:

- (a) a portion of a glasshouse, crossing shed or photoperiod facility;
- (b) a portion of outdoor area for germinating setts and seedlings on seedling benches and for cultivation of GM Sugarcane in pots or trays;
- (c) a germination chamber.

32. Within the Crossing Facility:

- (a) GM Sugarcane plants must be planted in pots or trays, except for cut inflorescences in the crossing shed;
- (b) GM Sugarcane plants and cut GM inflorescences must be clearly labelled as containing GM Sugarcane, and must be separated from non-GM Sugarcane, with the exception of those used for crossing, by a distance of at least 1 metre;

- (c) any non-GM Sugarcane within 1 metre of GM Sugarcane or GM inflorescence must be handled and controlled as if it were the GMOs;
- (d) GM Sugarcane seed may be germinated.

Note: For other conditions relevant to pollen transfer see condition 36.

Planting Areas

33. For each Planting Area, one of the following measures to contain the GMOs must be adopted:

- (a) each Planting Area must be surrounded with a Guard Row and an Isolation Zone (see Planting Area layout 1); or
- (b) individual Planting Areas must be separated with a Guard Row and all adjacent Planting Areas surrounded with at least one Guard Row and an Isolation Zone (see Planting Area layout 2).

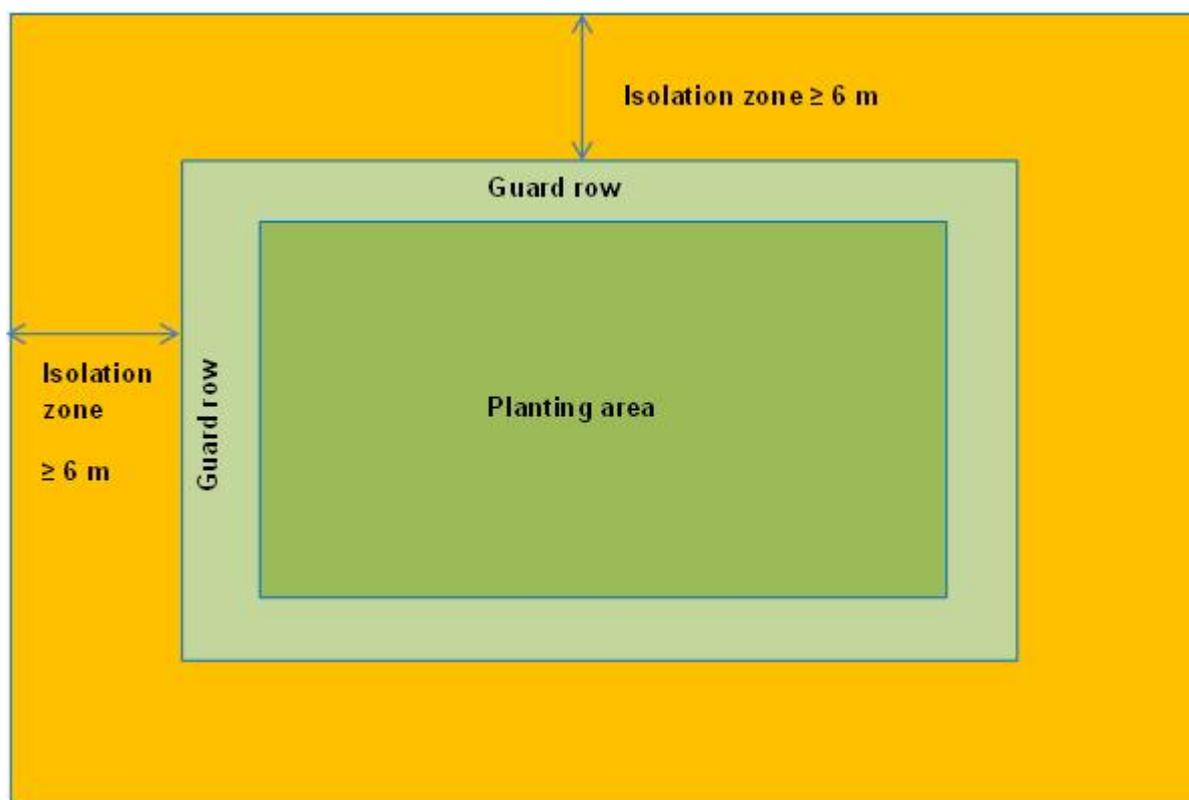


Figure 1 Planting Area layout 1 showing the relationship between a Planting Area, a Guard Row and an Isolation Zone (not drawn to scale).

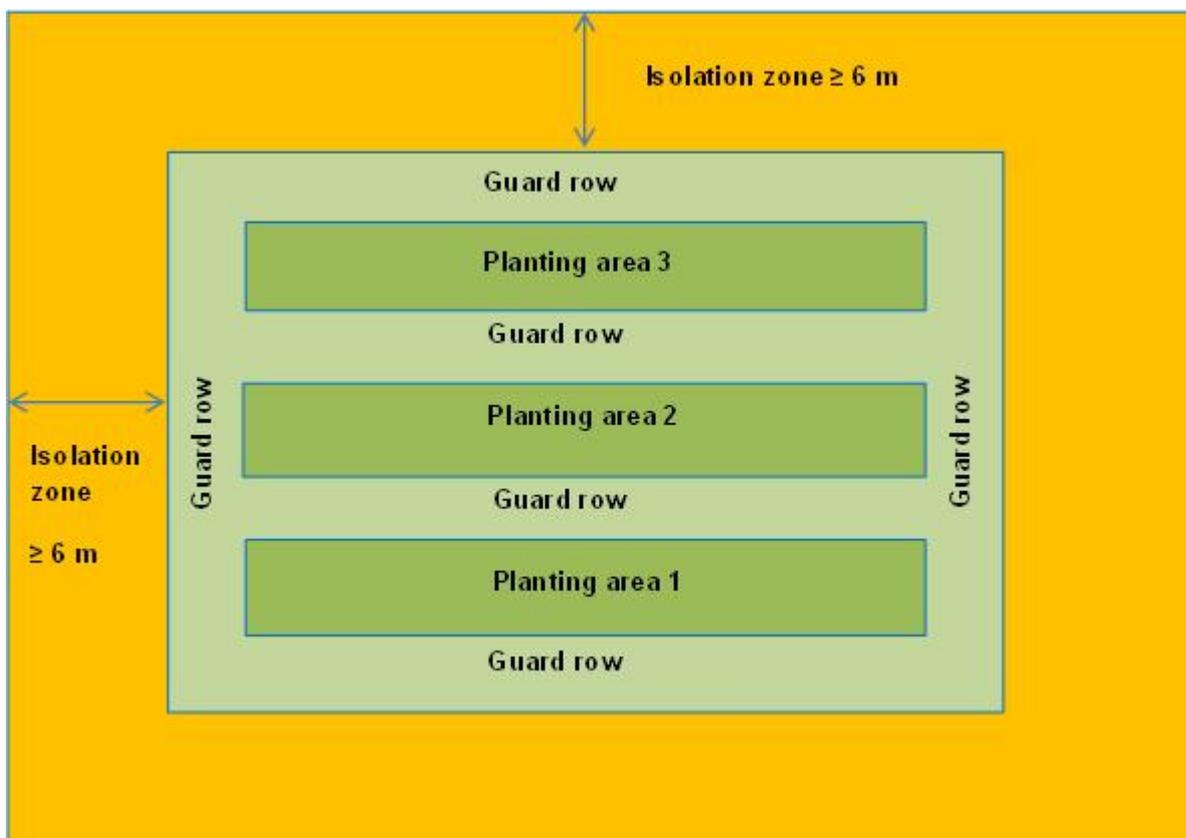


Figure 2 Planting Area layout 2 showing the relationship between a Planting Area, a Guard Row and an Isolation Zone (not drawn to scale).

34. 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 Planting Areas. This could be achieved by keeping the Isolation Zone free of any vegetation.

35. If any Sugarcane or Related Species occur in the Isolation Zone while the GMOs are being grown at a Planting Area, the Sugarcane or Related Species must be Destroyed immediately.

Inspections while growing, raising, culturing, breeding and propagating the GMOs

36. While the GMOs are growing, inspections must be conducted by people trained to recognize flowering stages of Sugarcane, Volunteers and Related Species, and actions taken, as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
(a) Planting Area, Guard Row	From the day of planting until the Planting Area is Cleaned.	At least every 35 days	Related Species	Destroy Related Species immediately.
(b) Isolation Zone	From the day of planting until the Planting Area is Cleaned.	At least every 35 days	Volunteers & Related Species	Destroy Volunteers and Related Species immediately.

Area	Period of inspection	Inspection frequency	Inspect for	Action
(c) Crossing Facility	From the actual date of commencement of Flowering of the GMOs in the facility* until the end of Flowering.	Three times per week	Spikelet opening	Implement the following control measures: Remove and Destroy GM Sugarcane inflorescences prior to spikelet opening; or Completely enclose GM Sugarcane inflorescences with pollen-impermeable lanterns with opening tied up, prior to spikelet opening.

**Condition 65(a) requires the licence holder to provide information to the Regulator on the expected flowering period, however the inspection period should be based on the observed development of the GMOs, so that inspections commence prior to flowering of any GMOs.*

Note: Details of any inspection activity must be recorded in a Logbook as detailed in Condition 66.

Section 4 Experimentation

37. If experimentation or analysis with the Plant Material is not conducted in accordance with Notifiable Low Risk Dealings (NLRD) requirements, experimentation or analysis with the Plant Material (including storage) may only be undertaken within:

- (a) a Planting Area; or
- (b) a Facility.

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.

38. Any Plant Material that is collected for experiments and/or analysis must be Destroyed as soon as practicable after use.

Section 5 Transport of Plant Material

39. If transport of Plant Material is not conducted in accordance with NLRD requirements, transport of Plant Material may only be undertaken according to:

- (a) the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs for PC2 GM plants as current at the time of transportation; or
- (b) conditions 40 and 41 when transport is conducted within a SRA station.

40. Plant Material (except cut inflorescences) being transported must:

- (a) be in bundles, seedling trays or pots;
- (b) have each bundle, tray, or pot labelled (eg with a barcode);
- (c) be transported in a covered trailer or weigh truck; and

- (d) have the transport vehicle followed and observed to ensure that no stalk material is lost during transportation.

41. GM Sugarcane inflorescences being transported must:

- (a) be labelled (eg with a barcode);
- (b) be completely enclosed in pollen impermeable material if shedding pollen (to prevent pollen escape); and
- (c) have the transport vehicle followed and observed to ensure no inflorescences are lost during transportation.

Note: Movement of Plant Material within areas under this licence is not regarded as transport or subject to restrictions, provided that it is carried out prior to Cleaning of those areas. For example, prior to Cleaning a Planting Area, Harvested Plant Material may be moved from the Planting Area, 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.

42. Plant Material may only be transported to the extent necessary to conduct the dealings permitted under this licence or under another relevant authorisation under the Act.

43. Methods and procedures used for any transportation of Plant Material must be recorded, and must be provided to the Regulator, if requested.

Section 6 Harvest, Cleaning, Disposal and Storage

Harvest procedures

44. Any GMO Harvested must be kept separate from any other Sugarcane plants or materials.

45. GM Sugarcane plants may be Ratooned following Harvest.

46. If all GMOs at a Planting Area are Destroyed, they are taken to have undergone Final Harvest for the purposes of this licence, and all conditions applying to post-Final Harvest apply equally to post-Destruction.

47. Harvesting must be conducted in a manner so as to avoid dispersal of Plant Material outside an area requiring Cleaning.

Cleaning of Equipment, Facilities and areas of land

48. Cleaning of Equipment and Facilities 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).

49. In the case of Equipment used at a Planting Area, Guard Row or Isolation Zone surrounding a Planting Area, the Equipment must be cleaned before it is removed from the area.

For example, if a mechanical harvester is used at a Planting Area, it must be Cleaned before it is moved off the Planting Area, Guard Row or Isolation Zone surrounding a Planting Area.

50. Following Final Harvest, the following areas of land used in connection with the GMOs must be Cleaned:

- (a) The Planting Area, Guard Row and Isolation Zone surrounding the Planting Area;
- (b) Any areas onto which GM Plant Material may have been dispersed; and
- (c) Any areas used to Clean Equipment or Destroy the GMOs.

51. With the exception of the Holding Area, each area of land in respect of each Planting Area must be Cleaned within 14 days of Final Harvest or Destruction.

Note: Cleaning activities must be recorded and reported to the Regulator (Section 8).

Holding Area

52. Plant Material may be stored at a Holding Area prior to Destruction and must be Destroyed as soon as practicable.

Note: In the above condition, depending on the Destruction method chosen, ‘as soon as practicable’ could have the effect of allowing the Plant Material to be left to dry before Destruction, eg by burning.

53. A maximum of one Holding Area may be located within each SRA station described in Condition 23.

54. A Holding Area must be surrounded by a fence with chicken wire to at least 1 metre and a functional electric fence strand until Destruction of the Plant Material

55. A Holding Area may also be used to store and then Destroy Plant Material from GM sugarcane authorised by the Regulator under a separate licence held by SRA.

56. If all Plant Material in a Holding Area is Destroyed, the area is taken to have been Cleaned for the purpose of this licence.

Inspections post-Cleaning and at Holding Areas

57. Areas of land must be inspected by people trained to recognise Volunteer Plants and Related Species as follows:

Area of land	Period of inspection	Inspection frequency	Inspect for	Action
(a) Planting Areas, associated Guard Row and Isolation Zone	From the day of completion of Cleaning 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 35 days	Volunteers and Related Species	Destroy Volunteers and Related Species as soon as practical and before Flowering.
(b) Other areas that have been Cleaned	iii. From the day of Cleaning until the Regulator has issued a Sign-off.			
(c) Holding Area	From the day Plant Material is placed in the Holding Area until the Regulator has issued a Sign-off	At least once every 35 days	(i) Volunteers and Related Species; (ii) damage to the fence	Destroy Volunteers and Related Species as soon as practical and before Flowering; Repair any damage

Other Storage

58. GM Sugarcane, its seed or other Plant Material may be stored in a container at a Facility provided the container is locked when unattended.

59. Plant Material may be stored in a Hot Water Treatment tank prior to planting, provided the Plant Material is completely enclosed in shade cloth, labelled as GM Plant Material and access to the tank is restricted to authorised people.

Section 7 Use of areas post-Harvest and Sign-off

General conditions on use of areas post-Harvest

60. No plants may be grown in an area of land following its Cleaning unless the Regulator has issued a Sign-off or unless the plants are plants agreed to in writing by the Regulator.

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

62. All areas of land requiring post-Harvest inspections must be maintained in a manner appropriate to allow the identification of any Volunteer Plants and Related Species.

63. Inspection requirements do not apply in respect of an area of land if the licence holder has received a Sign-off.

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

Sign-off

64. The licence holder may make written application to the Regulator that inspection requirements no longer apply to an area if:

- (a) All post-Cleaning inspection activities have been conducted for at least 12 months on the area and all associated areas of land; and
- (b) no Volunteers have occurred on these areas in the most recent six month inspection period.

Note: Associated areas refers to a Planting Area and the aggregate of all other areas of land requiring post-Cleaning inspections in respect of that Planting Area. Associated areas will be signed-off as a group rather than individually. The Regulator will take into account the management and inspection history for all associated areas in deciding whether or not she is satisfied that no further inspections are required to manage persistence of the GMOs.

Section 8 Reporting and Documentation

The following licence conditions are imposed to demonstrate compliance with other conditions and to facilitate monitoring of compliance by staff of the OGTR.

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

Notice	Content of notice	Timeframe
(a) Intention to Plant	<ul style="list-style-type: none">i. Details of the Planting Area including size, GPS coordinates and street address or other descriptionsii. Identity of the GMOs to be plantediii. Date on which the GMOs will be plantediv. Period when the GMOs are expected to Flower	At least 7 days prior to each planting (to be updated immediately if the notified intended planting dates change).

Notice	Content of notice	Timeframe
	<ul style="list-style-type: none"> v. Period when harvesting is expected to commence vi. For Planting Areas, the number of likely Ratoons vii. 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 viii. How the Planting Area is intended to be used during first two years following harvest. 	
(b) Intention to plant at Nurseries	<ul style="list-style-type: none"> i. Details of the Nursery including size, GPS coordinates, LGA and street address or other descriptions; ii. Identity of the GMOs planted, including where they originated; iii. Date on which the GMOs will be planted. 	At least 7 days prior to each planting.
(c) Planting	<ul style="list-style-type: none"> i. Actual date(s) of Planting the GMOs ii. Any changes to the details provided under condition 65(a) 	Within 7 days of any planting.
(d) Intent to Cross	<ul style="list-style-type: none"> i. the period during which crosses are expected to be undertaken 	At least 7 days prior to each crossing (to be updated as soon as practicable if the notified intended crossing or its date changes).
(e) Crossing	<ul style="list-style-type: none"> i. commencement of crossing 	
(f) Harvest	<ul style="list-style-type: none"> i. Actual date(s) of Harvesting the GMOs. 	Within 7 days of commencement of any Harvesting.
(g) Cleaning	<ul style="list-style-type: none"> i. Actual date(s) on which any areas needing Cleaning were Cleaned. ii. Method of Cleaning. 	Within 7 days of completion of any Cleaning.
(h) Holding Area	<ul style="list-style-type: none"> i. GPS coordinates before use 	7 days before use
(i) Holding Area	<ul style="list-style-type: none"> i. Date (s) of each addition of Plant Material 	Within 7 days of addition of Plant Material
(j) Holding Area	<ul style="list-style-type: none"> i. Date (s) on which Plant Material is Destroyed 	Within 7 days of Destruction of Plant Material
(k) Inspection activities	<ul style="list-style-type: none"> i. Information recorded in a Logbook as per the inspection requirement tables. 	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), 17 and 67.

66. 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 inspection;
- (c) details of the experience, training or qualification that enables the person(s) to recognise Sugarcane Volunteers and Related Species, if not already recorded in the logbook;
- (d) details of areas inspected including current land use (including details of any post-harvest crops grown pursuant to this licence), and recent management practices applied;

Note: this may also include irrigation, spraying or maintenance measures used to facilitate inspections for Volunteers/Related Species

- (e) details of any post-Harvest rainfall events including measurements at or near the area, or any irrigation events;
- (f) details of any post-harvest Volunteers observed including number, developmental stage and approximate position of the Volunteers with each area inspected[¶]; and
- (g) date(s) and method(s) of Destruction of any Volunteers.

[¶] *Examples of acceptable ways to record the positional information for Volunteers and Related Species in the Logbook include:*

- *Descriptive text*
- *Marking on a diagram*
- *Indicating grid references on corresponding map/sketch.*

67. Any extreme weather event that could potentially cause the dispersal of or has already led to the dispersal of GMOs or GM Plant Material from a Planting Area while the GMOs are growing or from any area while subject to Cleaning and inspection requirements, must be notified in writing to the Regulator as soon as practically and reasonably possible.

DIR No: 129

Full Title: Limited and controlled release of sugarcane genetically modified for herbicide tolerance

Organisation Details

Postal address: Sugar Research Australia
PO Box 86, 50 Meiers Road
Indooroopilly Qld 4068 Australia

Phone No: (07) 3331 3333

IBC Details

IBC Name: SRA Institutional Biosafety Committee

GMO Description

GMOs covered by this licence:

Saccharum spp. containing only the introduced genes specified below and the regulatory elements described in Table 1

Additionally, other GM sugarcane plants approved under Licence DIR 096 may also be dealt with under this licence if they occur as Volunteers but may not be intentionally planted.

Parent Organisms:

Common Names: Sugarcane
Scientific Names: *Saccharum spp.* Hybrid

Modified traits:

Categories: Herbicide tolerance
Description: Sugarcane plants have been genetically modified for herbicide tolerance.

Genetic elements responsible for conferring the modified trait:

Two herbicide tolerance (HT) genes are included in each GM sugarcane line. HT1, HT3 and HT4 are variants of a gene from a common soil bacterium, and HT2 is a gene from a common plant species. The identities of the introduced genes have been declared Confidential Commercial Information (CCI) and have been assigned a designation by the applicant.

Refer to Table 1 for promoters and other introduced genetic elements used in the GM sugarcane.

Purpose of the dealings with the GMOs:

SRA Limited has applied for a licence to release GM sugarcane lines into the environment on a limited scale and under controlled conditions. The purpose of the release is to evaluate the field performance of GM herbicide tolerant sugarcane and to conduct breeding to develop commercially useful GM herbicide tolerant sugarcane clones.

Table 1. Promoters and other introduced genetic elements used in the GM sugarcane

Name of genetic element	Function	Source gene	Source organism
<i>Ubi1</i>	Promoter	<i>Polyubiquitin gene</i>	<i>Zea mays</i>
<i>H2B</i>	Promoter	<i>Histone 2B</i>	<i>Zea mays</i>
<i>H2B-E</i>	Promoter	<i>Synthetic promoter comprised of Ubi1, H2B and CaMV 35S</i>	<i>Zea mays</i> and <i>Cauliflower mosaic virus</i>
<i>CaMV 35S</i>	<i>Enhancer</i>	<i>CaMV 35S gene</i>	<i>Cauliflower mosaic virus</i>
<i>Ubi1</i>	<i>Intron</i>	<i>Polyubiquitin gene</i>	<i>Zea mays</i>
<i>Nos</i>	<i>Terminator</i>	<i>Nopaline synthase gene</i>	<i>Agrobacterium tumefaciens</i>
<i>PinII</i>	<i>Terminator</i>	<i>Proteinase inhibitor II gene</i>	<i>Solanum tuberosum</i>

ATTACHMENT B

Checklist of documents that must be sent to the Regulator:

When	What	Condition	Timeframe
Prior to conducting any dealings	Details of organisations and persons covered	12(a)	
	Plan to inform people covered by the licence	12(b)	
	Plan to ensure control and access to all the Sites	12(c)	
	Detection methodology	12(d)	
	Contingency plan	12(e)	
Prior to planting	Intention to plant	65(a), (b)	At least 7 days prior to any planting (nursery or planting area)
During growing	Planting	65(c)	Within 7 days of any planting (nursery or planting area)
	Intent to Cross	65(d)	At least 7 days prior to each crossing (to be updated as soon as practicable if the notified intended crossing or its date changes)
	Crossing	65(e)	
	Harvest	65(f)	Within 7 days of commencement
Post-Cleaning	Cleaning	65(g)	Within 7 days of completion
	Holding Area GPS coordinates	65(h)	7 days before use
	Holding Area- each addition of Plant Material	65(i)	Within 7 days of addition of Plant Material
	Holding Area- Destruction of Plant Material	65(j)	Within 7 days of Destruction of Plant Material
	Inspection	65(k)	Within 35 days of each inspection
Any time after issue of the licence	Any changes of the project supervisor contact details	6	As soon as practically possible
	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)	12	Within 14 days of the changes
	Signed statements from persons covered under the licence	15(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 authorised by the licence	17	As soon as practically and reasonably possible, after becoming aware
	Extreme weather conditions	67	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport	43	If and when requested