



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 089

Licence holder: The Victorian Department of Primary Industries

Title: Limited and controlled release of white clover genetically modified for resistance to Alfalfa mosaic virus

Issued: 7 January 2009

Varied: 16 November 2009

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

Gene Technology Regulation in Australia

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

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

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

Other agencies that also regulate GMOs or GM products include Food Standards Australia New Zealand, Australian 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 089 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/dir089-2008>

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.

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.

'Bees' means cultivated honeybees of the species *Apis mellifera*.

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

- (i) 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
- (ii) in relation to Equipment, the removal and Destruction of the GMOs and Plant Material from the Equipment, to the reasonable satisfaction of the Regulator.

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

- (a) stalk pulling;

- (b) uprooting;
- (c) ploughing;
- (d) burning/incineration;
- (e) treatment with herbicide;
- (f) hand weeding;
- (g) autoclaving;
- (h) decomposition and deep burial

Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, in the case of plants with mature seed heads still attached ploughing would not be appropriate due to the introduction of large numbers viable seeds into the seedbank.

'Equipment' includes, but is not limited to, seeders, mowers, threshers, storage equipment, transport equipment (eg bags, containers, trucks), clothing and tools.

'Final Harvest' means the last collection of Plant Material.

'Flower' means a flower that can be pollinated or from which viable pollen can be transferred.

'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.

'Inner Pollen Trap' means an area of land extending at least one (1) metre in all directions from the outside edge of a Location.

'Isolation Zone' means an area of land extending outwards at least five hundred (500) metres in all directions from the outer edge of a Location but does not include the area planted to Pollen Traps or Pollen Buffers.

'Location' means the area of land where the GMOs or other plants may be intentionally planted and grown pursuant to this licence, but does not include the Pollen Traps, Pollen Buffer or Isolation Zone.

'Lucerne' means plants of the species *Medicago sativa* L.

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

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

'Outer Pollen Trap' means an area of land extending at least one (1) metre in all directions from the outer edge of a Pollen Buffer.

'Perennial ryegrass' means plants of the species *Lolium perenne* L.

'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.

'Pit' means a hole with a surface area of up to 8 m² located in the Pollen Buffer

'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 White clover or perennial ryegrass plants grown at the Location, or non-GM white clover grown in the pollen traps, whether viable or not, including, but not limited to, seed, stubble and pollen, whether from the plant itself or derived from or produced by the plant.

'Pollen Buffer' means an area of land extending at least thirty five (35) metres in all directions from the outer edge of the Inner Pollen Trap and which may contain one Pit.

'Pollen Buffer Plant' means non-GM Lucerne

'Pollen Trap Plant' means non-GM White clover

'Sign-off' means a notice in writing from the Regulator, in respect of a Site, that post Final Harvest inspection conditions no longer apply in respect of that Site.

'Site' means the aggregate of all Places for each Location.

'Volunteer Plants' means progeny or regrowth of the GMOs, or of non-GM White clover, grown at the Location.

'White clover' means plants of the species *Trifolium repens* L.

Section 2 General conditions

Duration of Licence

3. 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

4. The holder of this licence ('the licence holder') is the Victorian Department of Primary Industries.

Project Supervisor

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

6. 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

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

Persons covered by this GMO licence

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

Informing people of their obligations

9. 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.

10. 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.

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

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

Applicant to notify of circumstances that might affect suitability

13. 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

14. 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

15. 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.*

16. 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

17. 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.

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

Remaining an Accredited organisation

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

Notices

20. 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

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

Permitted dealings

22. 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

23. Non-GM White clover or non-GM Perennial ryegrass may be planted and grown at the Location but, if planted, must be handled and controlled as if it were the GMO (ie subject to other applicable conditions elsewhere in this licence).

24. Plant Material from non-GM White clover or non-GM Perennial ryegrass grown at a Location must be handled and controlled as if it were Plant Material from the GMO (ie subject to other conditions elsewhere in this licence).

Limits - locations, timing and size of trial

25. With respect to the permitted dealings described in condition 22, planting, growing, propagating, breeding and harvesting must only be undertaken between March 2009 and August 2011, inclusive, within the New South Wales local government area of Corowa.

26. No more than one Location may be used for each growing season and the maximum area for a Location is 633 m².

Notice of intention to plant, of planting and of Flowering

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

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

29. The licence holder must, in the manner required by condition 83, give notice to the Regulator of the actual date of commencement of each Flowering season of the GMOs.

Controls – planting and growing

30. The Location must be surrounded by an Inner Pollen Trap, a Pollen Buffer, an Outer Pollen Trap and an Isolation Zone while the GMOs are growing at the Location.
31. The Location and the Pit, if any, must be surrounded by a rabbit-proof fence. The fence must be inspected regularly and any damage allowing access by rabbits repaired immediately and reported to the Regulator.
32. The Outer Pollen Trap must be surrounded by a stock-proof fence with lockable gates, which must be locked except when the Location is accessed by persons covered by this licence. The fence must be inspected regularly and any damage allowing access by large animals, such as livestock, repaired immediately and reported to the Regulator.
33. Bee hives containing Bees may be situated in a Location for pollination while the GMOs, Pollen Buffer and Pollen Traps plants are Flowering.
34. Once pollination is complete, the bees, honey and pollen in the Bee hive must be destroyed.

Conditions related to Pollen Buffers and Pollen Traps

35. The Pollen Buffer must contain only Pollen Buffer Plants grown in such a way as to reasonably promote a dense and vigorous growth and in such a way as to ensure that the Pollen Buffer Plants have Flowers at the same time and for the same period of time as the GMOs.
36. The edge of the Outer Pollen Trap that is farthest from the GMOs (the ‘outer edge of the Outer Pollen Trap’) must not be within fifty (50) metres of a Natural Waterway.
37. The Inner Pollen Trap and Outer Pollen Trap must contain only Pollen Trap Plants grown in such a way as to reasonably promote a dense and vigorous growth and in such a way as to ensure that the Pollen Trap Plants have Flowers at the same time and for the same period of time as the GMOs.
38. With the exception of the area of the Pit, the Pollen Buffer and Pollen Traps must be planted and maintained in a way that ensures that for the duration of Flowering of the GMO(s) there is a continuous barrier of plants with Flowers at least thirty-seven (37) metres deep in all directions around the Location.
39. Pollen Buffer Plants and Pollen Trap Plants may be Destroyed after the end of each Flowering season. After Destruction the Pollen Buffer and Pollen Trap must be replanted and maintained in a way that ensures that there is a continuous barrier of plants with Flowers in place for each Flowering season until the GMOs have been Destroyed.
40. Pollen Trap Plants must be handled and controlled as if they were the GMOs (ie subject to other applicable conditions elsewhere in this licence), and Plant Material from Pollen Trap Plants must be handled and controlled as if it were Plant Material from the GMOs (ie subject to other applicable conditions elsewhere in this licence).

Section 4 Use of Plant Material

Experiment and storage

41. Experiments and/or analysis of Plant Material is only permitted if:
- (a) the experiment and/or analysis is a notifiable low risk dealing; and
 - (b) the experiment and/or analysis does not involve the feeding of the Plant Material to humans or animals.

Note: A dealing will only be a notifiable low risk dealing if:

- (a) *an Institutional Biosafety Committee has been asked to assess whether the proposed Dealing is a notifiable low risk dealing; and*
 - (b) *the Committee has assessed the proposed dealing to be a notifiable low risk dealing; and*
 - (c) *the person who proposes to undertake the proposed dealing and the project supervisor for the proposed dealing have been notified that the Committee;*
 - i) has assessed the proposed dealing to be a notifiable low risk dealing; and*
 - ii) considers that the personnel to be involved in the proposed dealing have appropriate training and experience.*
42. Any Plant Material that is collected for experiments and/or analysis may be transported off Site to:
- (a) a facility certified by the Regulator to PC2; or
 - (b) a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is stored within the facility;
- and may be experimented on and/or analysed and must be Destroyed as soon as practicable.

Plant Material not to be used in food

43. The GMOs, Plant Material, and products from the Beehives described in condition 33 must not be used, sold or otherwise disposed of for any purpose which would involve or result in their use as food for animals or humans.

Section 5 Transport, Cleaning and Disposal

Conditions relating to Destruction by decomposition and deep burial

44. If Destruction occurs by decomposition and deep burial the licence holder must:
- (a) Only dispose of vegetative Plant Material in the Pit;
 - (b) Ensure that the vegetative Plant Material placed in the Pit is immediately compacted and remains completely covered with soil to prevent dispersal; and
 - (c) At the end of the trial, completely fill in the Pit and ensure all Plant Material is covered by soil to a depth of at least 1 m.

Notice of Final Harvest and cleaning following Final Harvest

45. The licence holder must, in the manner required by condition 84, provide the Regulator with a notice of intention of Final Harvest of the GMOs at the Location.

46. The licence holder must, in the manner required by condition 85, provide the actual date or dates of Final Harvest of the GMOs at the Location.

47. The licence holder must, in the manner required by condition 86, give notice to the Regulator of the date on which Cleaning of the Place concluded.

Harvest and post-harvest procedures

48. If the GMOs or Plant Material from a Location are harvested, they must be harvested by hand or with a dedicated lawnmower.

Note: For the purpose of this licence, harvested by hand refers to the cutting of plant stems by hand with the aid of an implement which may include, but is not limited to, a hand sickle or secateurs.

49. If the GMOs or Plant Material from a Location are harvested, they must be harvested separately from any other crop.

50. If seed harvested from the GMOs or Plant Material is threshed, it must be threshed separately from any other crop.

51. If a thresher is used, appropriate measures must be in place to ensure that GM White clover seed or other Plant Material is not dispersed during threshing.

Transportation of Plant Material

52. Plant Material may only be transported to the extent necessary to store it, Destroy it, export it, Clean it from Equipment, relocate it to a facility approved by the Regulator or to a physical containment level 2 (PC2) facility, or relocate it to the Site from a facility approved by the Regulator or from a PC2 facility.

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

Cleaning of Equipment and Places

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

55. The following Places must be Cleaned:

- (a) the Location, Pollen Buffer, Inner Pollen Trap and Outer Pollen Trap;
- (b) irrigation channels and drains through which water flows to and from the Location;
- (c) any areas used during harvest, Final Harvest or threshing;

- (d) any areas used to Clean Equipment used in connection with the GMOs or Plant Material or to Destroy the GMOs or Plant Material.

56. Each Place in respect of the Location must be Cleaned within fourteen (14) days of Final Harvest of the GMOs.

Section 6 Inspection, Use of Site and Sign-off

57. Inspections must be performed by a person who is able to recognise Volunteer Plants.

Inspections to be conducted in the Pollen Buffer and Pollen Traps while the GMOs are being grown

58. Thirty five (35) days after the planting of the GMOs, as notified to the Regulator pursuant to this licence, the Pollen Buffer must be inspected for the presence of White clover plants.

59. Inspections of the Pollen Buffer must be conducted at least once every thirty five (35) days thereafter until the GMOs at the Location have been Destroyed.

60. If any White clover plants are found in the Pollen Buffer during the period when inspections of the pollen buffer are required to be conducted they must be Destroyed prior to having Flowers.

61. Fourteen (14) days before the expected commencement of each Flowering season of the GMOs at a Location, as notified to the Regulator pursuant to this licence, the Pollen Buffer and Pollen Traps must be inspected to determine whether the Pollen Buffer Plants and Pollen Trap Plants will Flower at the same time as the GMOs.

62. If less than 25% of the Pollen Buffer Plants are likely to produce Flowers at the same time as the GMOs are Flowering, the GMOs must be Destroyed or all flower buds must be removed from the GMOs to ensure there will be no GMO Flowers during this time.

63. Inspections for Flowers must be conducted at least once every fourteen (14) days thereafter and the condition in condition 62 applied until the GMOs at the Location have finished Flowering.

Inspections to be conducted in the Isolation Zone while the GMOs are being grown

64. Fourteen (14) days before the expected commencement of each Flowering season of the GMOs at a Location, as notified to the Regulator pursuant to this licence, the Isolation Zone must be inspected for the presence of White clover plants.

65. Inspections must be conducted at least once every thirty five (35) days thereafter until the GMOs at the Location have finished Flowering.

66. If any White clover plants occur in an Isolation Zone during the period when inspections of the isolation zone are required to be conducted, these White clover plants must be Destroyed prior to having Flowers.

General conditions on use of Location post-Final Harvest

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

68. After Final Harvest of the GMOs, the Location and the Inner Pollen Trap must be tilled, to the depth of the original planting, each Spring and each Autumn until such time as the licence holder has received a Sign-off in connection with the Location.

69. If, in Cultivating the Location and the Inner Pollen Trap, the soil does not contain sufficient moisture through accumulated rainfall or irrigation to cause the germination of Volunteer Plants, the licence holder must ensure that the Location and Inner Pollen Trap are irrigated sufficiently to cause the germination of Volunteer Plants.

Note: Any Volunteer Plants must be destroyed in a manner indicated elsewhere in this licence (eg destruction methods include herbicide application or up-rooting).

Post-Final Harvest Inspections

70. Following Cleaning, all Places Cleaned must be inspected for the existence of Volunteer Plants.

71. Any Volunteer Plants identified must be Destroyed prior to the plants Flowering.

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

73. The licence holder must, in the manner required by condition 88, record the results of inspection activities and forward the results to the Regulator.

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

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

Sign-off

75. For the Site if,

- (a) inspections have been routinely completed for a period of at least sixty (60) months, and
- (b) inspection records for that Site show that no Volunteer Plants have been observed in the most recent twelve (12) month inspection period.

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

Section 7 Reporting and Documentation Requirements

Compliance Management Plan

76. Prior to growing the GMOs, a written Compliance Management Plan must be provided to the Regulator. The Compliance Management Plan must describe in detail how the licence

holder intends to ensure compliance with each of these conditions and document that compliance and must include:

- (a) A list of the names of all organisations or natural persons who will be persons covered by this licence. Where a name of a person is not known at the time of submitting the Compliance Management Plan the function or position of the person to be covered must be provided.

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

- (b) An explanation of how the licence holder has informed, or proposes to inform, each person intended to be covered by the licence of the conditions of this licence including conditions related to the collection of Personal Information by the licence holder from the person intended to be covered by the licence.
- (c) A description of the responsibilities of the licence holder and of each person covered by the licence in relation to the requirements of this licence.
- (d) A description of how any contracts, agreements, or other enforceable arrangements between the licence holder and persons covered by the licence will allow the licence holder to access and control a Site to the extent necessary to comply with this licence, for the duration of the life of the licence.
- (e) A description of the licence holder's plans for post Final Harvest use of a Site during the life of this licence.

77. Where any of the details of the compliance management plan change, the Regulator must be notified of the changes within fourteen (14) days of the change occurring.

Contingency Plans

78. Within thirty (30) days of the date of issue of this licence, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event of the unintended presence of the GMOs or Plant Material outside an area that must be inspected.

79. The Contingency Plan must include details of procedures to:

- (a) ensure the Regulator is notified immediately if the licence holder becomes aware of the event;
- (b) Destroy any of the GMOs or Plant Material; and
- (c) inspect for and Destroy any Volunteer Plants that may exist as a result of the event.

80. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs or Plant Material is discovered outside an area that must be inspected.

Notice of intention to plant, of planting and Flowering

81. 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 White clover or Perennial ryegrass on a Location is intended to commence;
- (c) details of the Location where the GMOs will be planted, including the size of the Location, a street address and GPS coordinates for the Location;
- (d) the periods during which the licence holder considers the GMOs, Pollen Buffer and Pollen Traps are likely to be Flowering;
- (e) the periods during which the licence holder considers the GMOs are likely to be harvested;
- (f) the period(s) during which the licence holder considers Final Harvest of the GMOs will occur;
- (g) a description of how the Location is intended to be used during the first five years following Final Harvest of the GMOs.

82. 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 White clover or Perennial ryegrass on a Location occurred;
- (c) details of the Location where the GMOs were planted, including the size of the Location, a street address and GPS coordinates for the Location;
- (d) the periods during which the licence holder considers the GMOs, Pollen Buffer and Pollen Traps are likely to be Flowering;
- (e) the periods during which the licence holder considers the GMOs are likely to be harvested;
- (f) the period(s) during which the licence holder considers Final Harvest of the GMOs will occur;
- (g) a description of how the Location is intended to be used during the first five years following Final Harvest of the GMOs.

83. Within seven (7) days of the commencement of each Flowering season of the GMOs, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the actual dates on which Flowering of the GMOs, Pollen Buffer and Pollen Traps commenced;
- (b) the periods during which the licence holder considers the GMOs, Pollen Buffer and Pollen Traps likely to remaining Flowering;
- (c) the periods during which the licence holder considers the GMOs are likely to be harvested;
- (d) the period(s) during which the licence holder considers Final Harvest of the GMOs will occur.

Notice of Final Harvest and Cleaning following Final Harvest

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

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

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

87. On the request of the Regulator, the Regulator must be provided with written documentation of the procedures in place to ensure continuing compliance with the Cleaning conditions in this licence.

Results of inspection activities

88. The results of inspection activities must be recorded in a logbook or paper file. The findings of the inspections as recorded in the logbook or paper file must be forwarded to the Regulator within fourteen (14) days of inspection taking place and must also be included in the licence holder's Annual Report to the Regulator. The logbook or paper file must contain at least the following:

- (a) details of the areas inspected;
- (b) details of current land use (eg type of crop being grown) and of recent land management practices (eg irrigation, cultivation or spraying) applied in the areas inspected;
- (c) details of the date of inspection;
- (d) the names of the person or persons who undertook the monitoring and details of the experience, training or qualification that enabled them to recognise Volunteer Plants;
- (e) the means of inspection used;
- (f) the number of Volunteer Plants observed, if any;
- (g) details of the development stages reached by the Volunteer Plants, if any;
- (h) details of methods used to Destroy Volunteer Plants, if any;
- (i) details of any repairs to fences required under the conditions in conditions 31 and 32.

89. The licence holder must keep records of the area planted to the GM White clover line.

Annual Report

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

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 instrument must be provided within 30 days of the issuing of this licence.

DIR No: 089

***Full Title:** Limited and controlled release of GM white clover with resistance to Alfalfa mosaic virus

Organisation Details

Postal address: *Victorian AgriBiosciences Centre
1 Park Drive
Bundoora, VIC 3083
AUSTRALIA

Phone No: (03) 9479 2995

Project Supervisor Details

Surname: *[personal information – redacted]*

First Name: *[personal information – redacted]*

Title: *[personal information – redacted]*

Phone No: *[personal information – redacted]*

Fax: *[personal information – redacted]*

Email Address: *[personal information – redacted]*

Position: *[personal information – redacted]*

Organisation: The Victorian Department of Primary Industries

Postal Address: Victorian AgriBiosciences Centre
1 Park Drive
Bundoora, VIC 3083
AUSTRALIA

IBC Details

IBC Name: Department of Primary Industries - Victoria

GMO Description

The GMOs covered by this licence:

Trifolium repens genetically modified by introduction of only the genes, promoters and terminators listed below.

*Parent Organism(s):

Common Name: White clover

Scientific Names: *Trifolium repens* L.

*Modified trait(s):

Categories: Viral resistance

Description: White clover plants have been genetically modified for resistance to Alfalfa mosaic virus. All lines also contain a selective marker gene to identify transformed plant tissue.

*Genes responsible for conferring the modified trait:

Resistance to AMV *AMV CP* gene from Alfalfa mosaic virus

Selectable marker *nptII* gene from *Escherichia coli*

Promoters and terminators

Enhanced 35S promoter from CaMV

Nopaline synthase (*nos*) gene promoter from *A. tumefaciens*

rbc-E9 terminator from pea (*Pisum sativum*)

Nopaline synthase (*nos*) gene mRNA termination region from *A. tumefaciens*

Purpose of the Dealings with the GMOs:

The Victorian Department of Primary Industries applied for a licence to release 1 line of genetically modified (GM) white clover into the environment on a limited scale and under controlled conditions. The purpose of the trial is to conduct experiments to evaluate the agronomic performance, including seed yield, of the GM white clover line under field conditions. Some seed will be collected and retained for analysis and possible future trials, subject to further approval(s).

AMV causes a disease in white clover which reduces the productivity of white clover pastures. The purpose of investigating resistance to AMV is to improve the productivity of white clover pastures. The GM white clover will not be used for human food or animal feed.

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