



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 080/2007

Licence holder: Victorian Department of Primary Industries

Title: Limited and controlled release of wheat genetically modified for enhanced drought tolerance

Issued: 30 June 2008

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

Gene Technology Regulation in Australia

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

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

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

Other agencies that also regulate GMOs or GM products include Food Standards Australia New Zealand, Australian Pesticide and Veterinary Medicine Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme, National Health and Medical Research Council and Australian Quarantine and Inspection Service. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

The licence authorises the licence holder and persons covered by the licence to conduct specified dealings with the genetically modified organism(s) listed in Attachment B of this licence.

Dealings permitted by this licence may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Note about where dealings with GMOs are being undertaken pursuant to this licence

Information about where the GMOs have been planted pursuant to this licence can be found in a separate document entitled 'DIR 080/2007 Site Details'. This document can be viewed by accessing the document on the OGTR website at <http://www.ogtr.gov.au/ir/dir080.htm>.

Section 1 Interpretations and Definitions

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.

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.

'Burial Site' means a place where GMOs or Plant Material from the GMOs are Destroyed by burial under at least one (1) metre of soil.

'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.

'Deal With' in relation to a GMO means one or more of the following, as applicable:

- (a) conduct experiments with the GMO;
- (b) make, develop, produce or manufacture the GMO;
- (c) breed the GMO;
- (d) propagate the GMO;

- (e) use the GMO in the course of manufacture of a thing that is not a GMO;
- (f) grow, raise or culture the GMO;
- (g) transport the GMO;
- (h) dispose of the GMO;

and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (f)

'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) burial under at least one (1) metre of soil;
- (h) autoclaving.

Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, in the case of killing the remains of harvest of the GMOs, treatment of post harvest remains by herbicide would not be a sufficient mechanism.

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

'GM' means genetically modified.

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

'Isolation Zone' means, in respect of a Location, an area of land extending outwards at least one hundred and ninety (190) metres in all directions from the outer edge of the Monitoring Zone.

'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 Monitoring Zone or Isolation Zone.

'Monitoring Zone' means an area of land extending outwards at least ten (10) metres in all directions from the outer edge of a Location.

'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.

'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 Wheat plants grown at the Location, 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.

'Regulator' means the Gene Technology Regulator.

'Related Species' means plants in the genera *Triticum*, *Triticale*, *Hordeum*, *Secale*, *Aegilops* or *Elytrigia*.

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

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

'Triticaceae population' means groups of two or more plants per ten square metres of land belonging to the genera *Triticum*, *Aegilops* or *Secale*, or the species *Hordeum marinum*.

'Volunteer Plants' means progeny of the GMOs or non-GM Wheat grown at the Location, or regrowth of previous GM or non-GM wheat plants.

'Wheat' means plants of the species *Triticum aestivum* L.

Section 2 General conditions

Duration of Licence

1. 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

2. The holder of this licence ('the licence holder') is the Department of Primary Industries - Victoria

Project Supervisor

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

4. 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

5. Persons covered by this licence must not Deal With the GMOs except as expressly permitted by this licence.

Persons covered by this GMO licence

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

Informing people of their obligations

7. 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.

8. 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,
 - a. has been informed by the licence holder of the condition and, when applicable, its variation, and
 - b. has understood and agreed to be bound by the condition, or its variation, and
 - c. has not conducted the dealing without being informed of the condition, or its variation.

9. 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.

10. 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

11. 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

12. 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

13. 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.*

14. 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

15. 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.

16. 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

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

Notices

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

Section 3 Growing the GMOs

GMOs covered by this licence

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

Permitted dealings

20. The permitted dealings with the GMOs are to plant, grow, propagate, 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

21. Non-GM Wheat may be planted and grown at the Locations but, if planted, must be handled and controlled as if it were the GMO (ie subject to other applicable conditions elsewhere in this licence).

22. Plant Material from non-GM Wheat 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, growing seasons and size of trial

23. With respect to the permitted dealings described in condition 20, planting, growing, propagating and harvesting must only be undertaken between July 2008 and March 2010, inclusive, within the Victorian local government areas of Horsham and Mildura.

24. Intentional planting of the GMO must occur at no more than two Locations with a maximum combined area of 0.4 hectares in each year.

Notice of intention to plant, of planting and of flowering

25. The licence holder must, in the manner required by condition 80, give advance notice to the Regulator of an intention to plant the GMOs.

26. The licence holder must, in the manner required by condition 81, give notice to the Regulator of the actual date of planting the GMOs.

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

Controls – planting and growing

28. The outer edge of each Location must not be within fifty (50) metres of a Natural Waterway.

29. Each Location must be surrounded by a fence capable of excluding large animals, such as livestock, with lockable gates, which must be locked except when the Location is accessed by persons covered by this licence. The fences must be inspected regularly and any damage allowing access by large animals, such as livestock, repaired immediately and reported to the Regulator.

30. Each Location must be surrounded by a Monitoring Zone and an Isolation Zone.

31. The Monitoring Zone must be maintained in a manner that does not attract or harbour rodents while the GMOs are being grown at the Location within it, and until the site has been Cleaned. Measures to achieve this could include land free of any vegetation and/or vegetation kept mown to a height of less than ten (10) centimetres.

32. Appropriate measures must be implemented to control rodent numbers at each Location. These may include, but are not limited to, traps and/or poison bait within and/or surrounding a Location while GMOs are being grown at the Location and until the site has been Cleaned.

33. Any steps taken to control rodents and any evidence of rodent activity must be recorded in a log book and be available for inspection by the Regulator on request.

34. If any Related Species occur in a Monitoring Zone while the GMOs are being grown at the Location within it, either the Related Species or the GMOs in the Location must be Destroyed prior to flowering of the GMOs.

35. If any Triticaceae Population occurs in an Isolation Zone while the GMOs are being grown at the Location within it, either the Triticaceae Population or the GMOs in the Location must be Destroyed prior to flowering of the GMOs.

Section 4 Use of Plant Material

Experiment and storage

36. 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.*

37. 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

38. The GMOs and Plant Material 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 Cleaning and Disposal

39. If GMOs are Destroyed, they are taken to have been harvested for the purposes of this licence and all conditions applying to post-harvest apply equally to post-Destruction.

Notice of harvest and cleaning following harvest

40. The licence holder must, in the manner required by condition 83, provide the Regulator with a notice of intention to harvest the GMOs at each Location.

41. The licence holder must, in the manner required by condition 84, provide the actual date or dates of harvesting of the GMOs at each Location.

42. The licence holder must, in the manner required by condition 85, give notice to the Regulator of the date on which harvest of each location concluded.

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

Harvest and post-harvest procedures

44. If the GMOs or Plant Material from a Location are harvested, they must be harvested by hand, or through the use a plot harvester.

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.

45. If a plot harvester is used to harvest the GMOs; appropriate measures must be in place to ensure that GM wheat seed or other Plant Material is not dispersed during harvesting, and the resulting waste Plant Material collected and Destroyed through burning or deep burial.
46. If the GMOs or Plant Material from a Location are harvested, they must be harvested separately from any other crop.
47. If seed harvested from the GMOs or Plant Material is threshed, it must be threshed separately from any other crop.
48. If a thresher is used, appropriate measures must be in place to ensure that GM wheat seed or other Plant Material is not dispersed during threshing.

Transportation of Plant Material

49. 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.
50. 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

51. Cleaning of Equipment must occur immediately or as soon as practicable after use and before it is used for any other purpose.
52. The following Places must be Cleaned:
 - (a) the Location and Monitoring Zone;
 - (b) irrigation channels and drains through which water flows to and from the Location;
 - (c) any areas used during 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.
53. The Location and Monitoring Zone must be Cleaned before the end of the first May following each harvest. All other Places in respect to each Location must be cleaned within fifteen (15) days of harvest or Destruction of the GMOs.

Conditions relating to Destruction by burial

54. Subject to condition 37, if Destruction occurs by burial the licence holder must:
 - (a) within thirty (30) days of burial, provide the Regulator notice in writing of the precise location of the Burial Site (GPS coordinates and either a street address or other directions to the Location) and the date on which burial occurred; and
 - (b) inspect the Burial Site at least once every three (3) months for a period of two (2) years to identify:
 - i) any significant disturbance that may affect the emergence of Volunteer Plants and if disturbance is identified, notify the Regulator of appropriate remedial action taken; and

- ii) any emergence of Volunteer Plants. If Volunteer Plants are identified, the Burial Site must be Cleaned; and
- (c) report the findings according to condition 88.

55. Monitoring of the Burial Site is not required if burial takes place at a Municipal or commercial land fill and the Regulator is provided with a written notice from the manager of the land fill undertaking:

- (a) not to disturb the Burial Site for a period of at least two (2) years from the date of burial; and
- (b) to notify both the licence holder and the Regulator in writing of any significant disturbance of the Burial Site that may affect the emergence of Volunteer Plants.

Section 6 Inspection, Use of Site and Sign-off

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

Inspections to be conducted in the Location while the GMOs are being grown

57. Fourteen (14) days before the expected commencement of flowering of the GMOs at a Location, as notified to the Regulator pursuant to this licence, the Location must be inspected for the presence of Related Species that are not the GMOs.

58. If any Related Species that are not the GMOs are found they must be Destroyed before flowering.

59. Inspections must be conducted at least once every fourteen (14) days thereafter until the GMOs at the Location have finished flowering.

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

60. Fourteen (14) days before the expected commencement of flowering of the GMOs at a Location, as notified to the Regulator pursuant to this licence, the Monitoring Zone must be inspected for the presence of GMOs and Related Species.

61. Inspections must be conducted at least once every fourteen (14) days thereafter until the GMOs at the Location have finished flowering.

Note: Condition 34 requires the Destruction of the Related Species or the Cleaning of the Location if Related Species are found in the Monitoring Zone.

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

62. Fourteen (14) days before the expected commencement of flowering 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 Triticaceae Populations.

63. Inspections must be conducted at least once every fourteen (14) days thereafter until the GMOs at the Location have finished flowering.

Note: Condition 35 requires the Destruction of the Triticaceae Population or the Cleaning of the Location if a Triticaceae Population is found in an Isolation Zone.

General conditions on use of Location post-harvest

64. No plants may be intentionally planted and grown in a Place following harvest or 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.

65. Wheat stubble may be retained on the Location following harvest until the end of the first May following each harvest before being Destroyed.

Note: While some microbial degradation of the stubble may occur during this time, the GMOs and Plant Material must still be Destroyed as indicated elsewhere in this licence (eg Destruction methods include burning and up-rooting by ploughing) in order for the Location to be Cleaned.

66. The Location must be:

- (a) irrigated at least once within sixty days of each harvest; and
- (b) tilled and irrigated before the end of the first May following each harvest; and
- (c) tilled to the depth of the original cultivation and irrigated between twelve (12) and eighteen (18) months after the final harvest,

so as to promote the growth of Volunteer Plants.

Note: Written agreement from the Regulator must be obtained in order for a period of natural rainfall to be taken as an irrigation event. Any Volunteer Plants must be Destroyed in a manner indicated elsewhere in this licence (eg Destruction methods include the use of herbicides and up-rooting by ploughing).

67. The irrigations specified in condition 66 (a) and (b) must be separated by at least twenty eight (28) days.

Post-harvest (or post-Destruction) Inspections

68. Following harvest, all Places must be inspected for the existence of Volunteer Plants and/or related species.

69. All Places which must be inspected for the existence of Volunteer Plants and/or Related Species must be maintained in a manner appropriate to allow the identification of any Volunteer Plants and/or Related Species.

Note: The continued use of method(s) used to maintain the Monitoring Zone in a manner required under condition 31, may not be appropriate following harvest or Cleaning as these methods could interfere with the identification of Volunteers. For example, mowing to a height of less than 10 cm or herbicide treatment of weeds may inhibit identification of Volunteers.

70. Any Volunteer Plants or Related Species identified must be Destroyed prior to the plants flowering.

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

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

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

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

Sign-off

74. For each Site,

- (a) if inspections have been routinely completed for a period of at least twenty four (24) months, and
- (b) if inspection records for that Site show that no Volunteers have been observed in the most recent 6 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

75. Prior to growing the GMOs, a written Compliance Management Plan must be provided to the Regulator. The Compliance Management Plan must describe in detail how the licence holder intends to ensure compliance with each of these conditions and document that compliance and must include,

- (a) A list of the names of all organisations or natural persons who will be persons covered by this licence. Where a name of a person is not known at the time of submitting the Compliance Management Plan the function or position of the person to be covered must be provided.
Note: Examples of functions or positions are 'Site manager', 'Farm labourer' etc.
- (b) An explanation of how the licence holder has informed, or proposes to inform, each person intended to be covered by the licence of the conditions of this licence including conditions related to the collection of Personal Information by the licence holder from the person intended to be covered by the licence.
- (c) A description of the responsibilities of the licence holder and of each person covered by the licence in relation to the requirements of this licence.
- (d) A description of how any contracts, agreements, or other enforceable arrangements between the licence holder and persons covered by the licence will allow the licence holder to access and control a Site to the extent necessary to comply with this licence, for the duration of the life of the licence.
- (e) A description of the licence holder's plans for post harvest use of a Site during the life of this licence.

76. 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

77. 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.

78. 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.
79. 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

80. 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 Wheat on a Location is intended to commence;
- (c) details of each Location where the GMOs will be planted, including the size of the Location, a street address and GPS coordinates for each Location;
- (d) the identity 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) the period during which the licence holder considers the GMOs are likely to be Destroyed;
- (h) if GMOs have previously been planted at a Location, a history indicating how the Location has been used in the preceding two years, including details of previous GMOs and post-harvest crops planted at the Location; and
- (i) a description of how the Location is intended to be used during the first two years following harvest of the GMOs.

81. 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 Wheat 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 identity of the GMOs which were 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) the period during which the licence holder considers the GMOs are likely to be Destroyed;
- (h) a description of how the Location is intended to be used during the first two years following harvest of the GMOs.

82. Within seven (7) days of flowering of the GMOs, 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) the period during which the licence holder considers the GMOs are likely to be harvested;
- (d) the period during which the licence holder considers the GMOs are likely to be Destroyed.

Notice of harvest and Cleaning following harvest

83. The licence holder must provide the Regulator with a notice of intention to harvest the GMOs at each 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 set out in the notice. Any change of intention prior to the intended harvest date must be notified to the Regulator as soon as is reasonably and practically possible.

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

85. The licence holder must provide a notice in writing to the Regulator when harvesting of a Location is completed. The notice must be provided to the Regulator within fourteen (14) days of the date on which harvesting of the Location concluded.

86. The licence holder must provide a notice in writing to the Regulator when a Location is Cleaned following 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 any rainfall events at the location including measurements of any rainfall;

- (d) details of the date of inspection;
- (e) 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;
- (f) the means of inspection used;
- (g) the number of Volunteer Plants or Related Species observed, if any;
- (h) details of the development stages reached by the Volunteer Plants or Related Species, if any;
- (i) details of methods used to Destroy Volunteer Plants or Related Species, if any;
- (j) details of rodent control methods used, if any;
- (k) details of any repairs to fences required under condition 29.

89. The licence holder must keep records of the type of GM Wheat lines grown at the Site as part of the trial, and the area planted to each type.

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: 080/2007

***Full Title:** Limited and controlled release of wheat genetically modified for enhanced drought tolerance

Organisation Details

Organisation: *Department of Primary Industries - Victoria

Postal address: Primary Industries Research Victoria
Victorian Agrobiosciences Centre
1 Park Drive
Bundoora VIC 3083

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: Department of Primary Industries - Victoria

Postal Address: Primary Industries Research Victoria
Victorian Agrobiosciences Centre
1 Park Drive
Bundoora VIC 3083

IBC Details

IBC Name: Department of Primary Industries – Victoria

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

GMO Description***Parent Organism(s):**

Common Name: Bread Wheat
 Scientific Name: *Triticum aestivum* L. cv. Bobwhite 26

***Modified trait(s):**

Category: Enhancement of drought tolerance
 Herbicide tolerance

Description: Wheat plants have been genetically modified to show improved growth characteristics under low water conditions.

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

Enhanced drought tolerance *[This is Confidential Commercial Information]*
 Herbicide tolerance *bar* gene from *Streptomyces hygroscopicus*
 Selectable and visual markers *bla* gene from *Escherichia coli*

Purpose of the Dealings with the GMOs:

The Victorian Department of Primary Industries (DPI Victoria) applied for a licence to release up to 50 genetically modified (GM) wheat lines into the environment on a limited scale and under controlled conditions. The trial involves proof of concept research, including continuing assessment of some lines that were initially authorised for release under DIR 071/2006. The agronomic performance, including yield, of the GM wheat lines will be evaluated under rain-fed, drought prone conditions. Seed and tissue samples will be collected and retained for analysis and possible future trials of lines that may be selected for further development, subject to further approval(s). The GM wheat will not be used for human food or animal feed.

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