



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 102

Licence holder: The University of Adelaide

Title: Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance

Issued: 29 June 2010

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

Gene Technology Regulation in Australia

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

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

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

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

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

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

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

Information about where the GMOs have been planted pursuant to this licence can be accessed on the OGTR website at
<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir102>

Section 1 Interpretations and Definitions

1. This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.
2. In this licence:
 - (a) unless defined otherwise in this licence, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;
 - (b) words importing a gender include any other gender;
 - (c) words in the singular include the plural and words in the plural include the singular;
 - (d) words importing persons include a partnership and a body whether corporate or otherwise;
 - (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;
 - (f) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;
 - (g) specific conditions prevail over standard conditions to the extent of any inconsistency.
3. In this licence:

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

'Annual Report' means a written report provided to the Regulator within 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.

'Barley' means plants of the species *Hordeum vulgare* L.

'Break Crop Plants' means plants agreed to in writing by the Regulator.

'Buffer Zone' means an area of land extending outwards at least 2 metres from the outer edge of a Location.

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

- (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.

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

- (c) uprooting;
- (d) ploughing;

- (e) burning/incineration;
- (f) treatment with herbicide;
- (g) autoclaving; or
- (h) 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, 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, plot harvesters, threshers, storage equipment, transport equipment (eg bags, containers, trucks), clothing and tools.

'Fenced Area' means an area surrounded by a fence, containing the Location and the associated Buffer Zone (see Figure 1).

'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.

'Inspection Zone' means an area of land extending outwards from the outer edge of the Monitoring Zone the distance specified elsewhere in this licence (see Figure 1).

'Isolation Zone' means an area of land extending outwards at least 190 metres in all directions from the outer edge of the Monitoring Zone (see Figure 1).

'Location' means an area of land where the GMOs or other plants are planted and grown pursuant to this licence (see Figure 1).

'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 Regulator on request.

'Monitoring Zone' means an area of land extending outwards at least 10 m from the Fenced Area (see figure 1).

'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 of land which will require Cleaning, or which has been Cleaned, pursuant to this licence (see Figure 1).

'Plant Material' means any part of the GM or non-GM Wheat or Barley plants grown at a Location or Buffer Zone, including, but not limited to, seed, stubble and pollen, whether from the plant itself (whether viable or not) or derived from or produced by the plant.

'Population' means 2 or more plants per 10 square metres of land.

'Related Species' means plants of the species *Hordeum vulgare* L. and plants in the genus *Triticum*, including *Triticum aestivum* L., but not including the GMOs and non-GM wheat and barley plants planted and grown according to this licence.

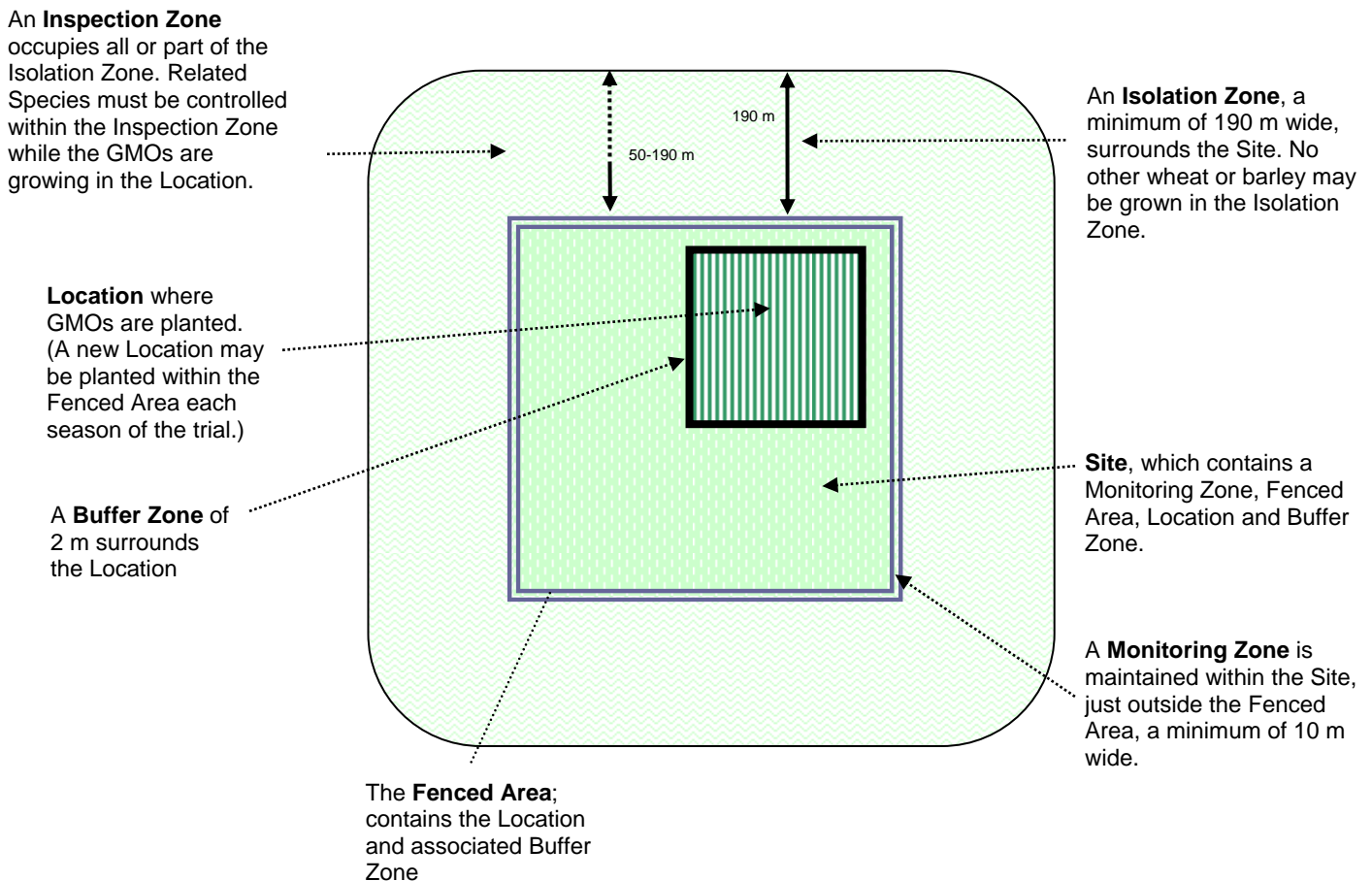
'Sign-off' means a notice in writing from the Regulator, in respect of a Site, that post harvest inspection obligations no longer apply in respect of that Site.

'Site' means an area of land containing a Monitoring Zone and a Fenced Area within which a Location may be established (see Figure 1).

'Volunteers' means GM or non-GM Wheat and Barley plants which have not been intentionally grown.

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

Figure 1. Diagram showing the relationship between a Site, a Fenced Area, a Location, a Monitoring Zone, an Inspection Zone and an Isolation Zone (not drawn to scale).



Section 2 General conditions

Duration of licence

4. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with GMOs are authorised during any period of suspension.

Holder of licence

5. The holder of this licence ('the licence holder') is the University of Adelaide.

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

Project supervisor

7. The project supervisor in respect of this licence is the person named in Attachment A of the licence.

8. 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

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

Persons covered by this GMO licence

10. 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

11. 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.

12. 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.

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

14. Prior to growing the GMOs the licence holder must provide to the Regulator an explanation of how the licence holder has informed, or proposes to inform, each person intended to be covered by this licence of the conditions of the licence including conditions related to the collection of Personal Information by the licence holder.

15. Where any of the details provided under the immediately preceding condition change, the Licence holder must notify the Regulator of the changes within fourteen days of the change occurring.

16. The licence holder must notify the project supervisor and all persons covered by the 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.

Additional information to be given to the Regulator

17. The licence holder must immediately, by notice in writing, inform the Regulator of:
- (a) any relevant conviction of the licence holder occurring after the commencement of this licence; and
 - (b) any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment; and
 - (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it.
18. 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.
19. The licence holder must inform 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.*
20. 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.
21. Prior to growing the GMOs, the licence holder must provide to the Regulator:
- (a) a list of the names of all organisations or natural persons who will be persons covered by this licence. Where a name of a person is not known at the time of submitting the list, the function or position of the person to be covered must be provided, and
 - (b) a description of the responsibilities of the licence holder and of each person covered by the licence in relation to the requirements of this licence.

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

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

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

23. 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.

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

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

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

Section 3 Growing the GMOs

GMOs covered by this licence

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

Permitted dealings

28. The permitted dealings with the GMOs are to conduct experiments with the GMOs, breed, propagate, grow, culture, transport and dispose of the GMOs, use the GMO in the course of manufacture of a thing that is not a GMO, and the possession, supply and use of the GMOs in the course of any of these dealings.

Non-GM Plants

29. Non-GM Wheat and Barley, and Plant Material from non-GM Wheat and Barley, grown at the Location and Buffer Zone must be handled and controlled as if they are the GMOs or Plant Material from the GMOs.

Limits - Locations, growing season and size of trial

30. With respect to the permitted dealings described in condition 28, planting, growing, propagating, culturing and harvesting must only be undertaken between the date of issue of this licence and December 2015, inclusive, within a single Site in each of the local government areas of Marion and Wakefield in South Australia and Corrigin in Western Australia..

31. Intentional planting of the GMOs must only occur at one Location per growing season, within each Site, and the maximum total area planted must not exceed 7500 m² (0.75 hectare) per growing season.

Containment measures

32. The outer edge of a Location must not be within fifty metres of a Natural Waterway.

33. A Location must be surrounded by a Buffer Zone, which may consist of:

- (a) an area free of any vegetation and/or vegetation kept mown to a height of less than ten centimetres;
- (b) any species that is not a Related Species; or
- (c) non-GM Wheat or non-GM Barley, provided they are not allowed to produce viable seed.

34. A Location and associated Buffer Zone must be within a Site.
35. The Fenced Area must be surrounded by a fence capable of excluding livestock, with lockable gates which must be locked except when accessed by persons covered by this licence.
36. Measures must be implemented to control rodent numbers in the Fenced Area. These may include, but are not limited to, traps and/or poison bait within and/or surrounding the Fenced Area while GMOs are being grown and until the Site has been Cleaned.
37. The Fenced Area must be surrounded by a Monitoring Zone, and the Monitoring Zone must be surrounded by an Inspection Zone and an Isolation Zone.
38. The Monitoring Zone must be maintained in a manner that does not attract or harbour rodents while the GMOs are being grown at a Location, and until the Location is Cleaned. Measures to achieve this could include land free of any vegetation and/or vegetation kept mown to a height of less than 10 centimetres.
39. Any steps taken to control rodents and any evidence of rodent activity must be recorded in a Logbook.
40. The Inspection Zone must extend outwards from the outer edge of the Monitoring Zone by at least:
- (a) 190 metres; or
 - (b) 50 metres, if:
 - (i) no Wheat or Barley has been grown in the Isolation Zone for the last 2 years; and
 - (ii) no Populations of Related Species have been observed during inspections conducted under conditions 64 and 67 in the previous growing season; and
 - (a) it is agreed to in writing by the Regulator;
41. The Licence holder must not permit Related Species to be planted within the Isolation Zone while the GMOs are growing in the Location.
- Note: Other conditions of this Licence require inspections for, and control of, Related Species in the Location, Buffer Zone, Monitoring Zone, other areas with the Site and Inspection Zone while the GMOs are growing in the Location (Section 7 – Inspections).*
42. Other than within a Location, only Break Crop plants may be grown within a site, and any Break Crop plants must be either:
- (a) managed so as to not interfere with detection and destruction of Volunteers and Related Species; or
 - (b) treated with selective herbicide such that any Related Species and Volunteers growing amongst the Break Crop Plants would be Destroyed prior to flowering.

Section 4 Use of Plant Material

Plant Material not to be used in food or animal feed

Note: This licence does not expressly authorise or prohibit any dealings or storage in certified physical contained facilities. Under the Act it is not an offence to deal with a GMO if the dealing is otherwise licensed or if it is an NLRD or an exempt dealing and it complies with all relevant statutory requirements.

43. 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 humans or feed for animals, or in the production of therapeutic goods.

Experimentation and storage

44. Plant material collected or harvested from a Location may be used for experimentation or analysis, provided experimentation and analysis of Plant Material takes place:

- (a) within a Location; or
- (b) in a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is present within the facility.

45. Plant Material used for experimentation or analysis must be Destroyed as soon as practicable after use.

46. Plant Material may be stored off Site in a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is stored within the facility. Stored Plant Material must be contained within a sealed, unbreakable container that is clearly labelled so as to indicate the contents.

Transportation of Plant Material

47. Plant Material may only be transported to the extent necessary to store it, Destroy it, Clean it from equipment, export it, conduct experiments or analysis on it, transfer it to a Location or relocate it for the purpose of conducting dealings pursuant to another relevant authorisation under the Act.

48. Any Plant Material transported outside a Site must be transported in accordance with the Regulator's *Guidelines for the Transport of GMOs* as current at the time of transportation.

Section 5 Harvest, Cleaning and Disposal

Harvest and post-harvest procedures

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

50. If the GMOs or non-GM plants from a Location are harvested, they must be harvested separately from any other crop.

51. If the GMOs or Plant Material from a Location are harvested, they must be harvested by hand, or through the use of a single-row or 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 scateurs.

52. If seed harvested from the GMOs or Plant Material is threshed, it must be threshed separately from any other crop and threshing must take place within the Location.

53. During harvesting, and during threshing, Plant Material must not be dispersed outside the buffer zone.

Note: Threshing may also be conducted in a certified facility as a notifiable low risk dealing, in accordance with all applicable requirements of the Gene Technology Regulations 2001, as dealings conducted as notifiable low risk dealings are not subject to conditions of this licence

54. Cleaning of Equipment used in connection with the GMOs must occur as soon as practicable after use and before it is used for any other purpose, and Cleaning of equipment

used within a Location or Buffer Zone must occur within the Site, so as to prevent dispersal of viable Plant Material.

55. The following Places must be Cleaned:

- (a) Locations;
- (b) Buffer Zones;
- (c) any areas onto which Plant Material was dispersed during harvest or threshing;
- (d) any areas used to Clean Equipment used in connection with the GMOs or Plant Material; and
- (e) any areas used to Destroy the GMOs or Plant Material.

56. Places other than the Location and Buffer Zone must be Cleaned as soon as practicable after use and before they are used for any other purpose.

57. The Location and associated Buffer Zone must be Cleaned before the end of the first May following harvest of the GMOs in the Location.

Note: Other conditions of this Licence require the Licence Holder to make records and give notices to the Regulator in relation to Cleaning of Sites (Section 8 – Reporting and Documentation Requirements).

Section 6 Conditions on use of Locations after harvest and Places after Cleaning

General conditions on use of Location post-harvest

58. The Location and associated Buffer Zone must not be tilled for at least 28 days after the GMOs at the Location are harvested, so as to promote after-ripening of grain remaining on the soil surface.

59. Following Cleaning, each Place must be maintained in a manner appropriate to allow the identification of any Volunteer Plants and Related Species as long as inspections are required for the Site.

60. No plants may be intentionally grown in a Place following its Cleaning unless:

- (a) the plants are the GMOs, non-GM Wheat or non-GM Barley planted in accordance with the conditions of this licence; or
- (b) the plants are Break Crop Plants; or
- (c) the Regulator has issued a Sign-off for the Site.

Note: Break Crop plants are subject to management requirements according to condition 42.

61. Prior to an application for Sign-off in respect of a Site, all Places in respect of the Site must receive at least 3 irrigations, at intervals of at least 28 days. The first irrigation must occur within the first 60 days after harvest in each Place. The last irrigation must occur at a time that would promote germination of Volunteers within the Volunteer-free period immediately prior to the Sign-off application.

Note: A period of natural rainfall may be taken as irrigation only with the agreement of the Regulator.

62. Prior to the last irrigation referred to in the immediately preceding condition, all Places in the Site must be tilled to a depth no greater than the depth of sowing.

Section 7 Inspections

63. Inspections must be performed by a person who is able to recognise Volunteer Plants, and Related Species. Details of the experience, training or qualification that enables them to recognise Volunteers and Related Species must be provided to the Regulator within 14 days of their first inspection.

Note: Results of inspection activities are required to be provided to the Regulator (see Section 8 – Reporting and Documentation Requirements).

Inspections to be conducted while the GMOs are being grown

64. Inspections must be conducted in the Inspection Zone at least once every 14 days, beginning 14 days before the expected commencement of flowering of the GMOs at a Location until the GMOs in the Location have finished flowering.

65. Inspections of the Site, including the Location and Buffer Zone, the fence surrounding the Site and the Monitoring Zone must be conducted at least once every 14 days, beginning 14 days before the expected commencement of flowering of the GMOs at a Location and continuing until the Location and associated Buffer Zone has been Cleaned.

66. The Inspection Zone must be inspected for Related Species, and any Populations of Related Species found must be either Destroyed prior to flowering or prevented from flowering.

67. The Site must be inspected for the presence of Related Species, and any Related Species occurring in these areas must be either Destroyed before flowering or prevented from flowering.

68. The fence surrounding the Location must be inspected and any damage allowing access by large animals, such as livestock, repaired immediately.

Post-Cleaning Inspections

69. All Places must be inspected for Volunteers and Related Species at least once every 35 days commencing on the last day of Cleaning and continuing until:

- (a) the Place is replanted to the GMOs; or
- (b) the Regulator has issued a Sign-off for the Site.

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

Note: Results of inspection activities must be provided to the Regulator as required in Section 8 of this licence.

Sign-off

71. The licence holder may make written application to the Regulator that these inspection conditions no longer apply to a Site if post-cleaning inspections have been routinely completed for a period of at least 24 months and no Volunteers have been observed in the most recent 6 month inspection period.

Note: Licence conditions require one tillage and three irrigations or rainfall events for all Places prior to a Sign-off application (see Section 6 – Conditions on use of Locations after harvest and Places after Cleaning). The Regulator will take into account the management and inspection history for the Site, including tillage, irrigation regimes/rainfall events, management of any Break Crops and occurrence of volunteers, in deciding whether or not he is satisfied that no further inspections are required to manage persistence of the GMOs.

Section 8 Reporting and Documentation Requirements

Contingency Plans for unintended presence of Plant Material

72. Within 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.

73. 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
- (a) inspect for and Destroy any Volunteers that may exist as a result of the event.

74. 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

75. At least 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(s) on which planting of the GMOs is intended to commence;
- (b) the date on which planting of any non-GM Wheat or non-GM barley in the Location or associated Buffer Zone is intended to commence;
- (c) details of the Site and Fenced Area, including the GPS coordinates;
- (d) details of the Location, including the GPS coordinates and dimensions (in metres);
- (e) the identity of the GMOs which are intended to be planted;
- (f) the period during which the licence holder considers the GMOs are likely to flower;
- (g) the period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed in lieu of harvest);
- (h) the period(s) during which the licence holder considers the Location and associated Buffer Zone are likely to be Cleaned;
- (i) if GMOs have previously been planted at a Location, a history indicating how the Location has been used in the preceding 2 years, including details of previous GMOs and post-harvest crops planted at the Location; and
- (j) a description of how the Location is intended to be used during the first 2 years following harvest of the GMOs.

76. Within 7 days of planting of the GMOs, the licence holder must provide a notice in writing to the Regulator which indicates the actual date on which planting of the GMOs occurred and any changes in the details required to be provided under the preceding condition.

77. Between 21 and 7 days before the expected commencement of each flowering season of the GMOs, if any details provided under the preceding two conditions have changed the licence holder must provide a notice in writing to the Regulator indicating the changes.

78. Within 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 the actual date on

which flowering of the GMOs commenced and indicating any changes in the details under the preceding three conditions.

Notice of harvest and Cleaning

79. The licence holder must provide the Regulator with a notice of intention to harvest the GMOs at a Location. This notice must be provided at least 7 days, and not more than 21 days, in advance of the intended date of harvest set out in the relevant 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.

80. Within 7 days of commencement of harvesting of the GMOs at a Location, the licence holder must provide the actual date or dates of commencement of harvesting of the GMOs at a Location.

81. Within 14 days of the date on which Cleaning of a Place is completed, the licence holder must provide a notice in writing to the Regulator indicating the date or dates on which Cleaning was undertaken.

82. 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.

Notices of inspection activities

83. The results of all inspection activities must be recorded in a Logbook, and must include at least the following:

- (a) the date of inspection;
- (b) the names of the person or persons who undertook the inspection;
- (c) details of the areas inspected;
- (d) 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;
- (e) details of any rainfall events at the Location including measurements of any rainfall at or near the Location;
- (f) the means of inspection used;
- (g) the number of Volunteers or Related Species observed, if any;
- (h) details of the development stages reached by the Volunteers or Related Species, if any;
- (i) details of methods used to Destroy Volunteers or Related Species, if any, and the date(s) of Destruction, if different from the date of inspection;
- (j) details of rodent control methods used, if any;
- (a) details of any repairs required to the fence surrounding the Location.

84. The results of the inspections as recorded in the Logbook must be forwarded to the Regulator within 14 days of inspection taking place and must also be included in the licence holder's Annual Report to the Regulator.

Other records to be kept

85. The licence holder must keep records of the types of GM Wheat and GM Barley lines grown at each Location as part of the trial and the area planted to each GM Wheat and GM Barley line.

Annual Report

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

Note: Conditions 20 and 84 specify information that must be included in an Annual Report.

Testing methodology

87. The licence holder must provide a written instrument to the Regulator describing an experimental method that is capable of reliably detecting the presence of the GMOs and the presence of the genetic modifications described in this licence (for details see Attachment B of the licence) in a recipient organism. The detection method must be capable of reliably distinguishing between the different categories of GMOs described in this licence. The instrument must be provided within 30 days of the issuing of this licence.

DIR No: 102

***Full Title:** Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance.

Organisation Details

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SA 5005
AUSTRALIA

Phone No: (08) 8303 4455

Project Supervisor Details

Surname: [*Personal Information Redacted*]
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IBC Details

IBC Name: The University of Adelaide Institutional Biosafety Committee

GMO Description

GMOs covered by this licence:

Triticum aestivum and *Hordeum vulgare* containing the introduced genes and regulatory elements as described in Tables 1 and 2.

*Parent Organism:

Common names: Wheat and Barley

Scientific Names: *Triticum aestivum* cvs. Bob White, Drysdale and Frame

Hordeum vulgare cvs Golden Promise and WI4330

*Modified traits:

Categories: Drought, salt, low phosphorus and cold/frost tolerance

Zinc translocation

Nitrogen use efficiency

Antibiotic resistance

Description: Wheat and barley plants have been genetically modified for enhanced tolerance to a range of abiotic stresses. Up to 1161 lines of GM wheat and 1179 lines of GM barley may be released. Each line will contain one of 35 genes encoding proteins expected to confer tolerance to cold/frost, drought, salt and low soil phosphorus, to improve nitrogen use efficiency, or to enhance zinc uptake and translocation. The GM wheat and barley lines also contain the selectable marker gene *hpt*.

Purpose of the dealings with the GMOs:

The University of Adelaide has applied for a licence to release up to 2340 genetically modified wheat and barley lines into the environment on a limited scale and under controlled conditions. The purpose of the release is to conduct experiments to assess whether expression of the introduced genes for abiotic stress tolerance, nitrogen use efficiency and zinc biofortification results in increased yield in the GM wheat and barley plants when grown under field conditions. Some seed will be saved for possible future trials with promising lines. The GM wheat and barley will not be used for human food or animal feed.

*Genetic elements responsible for conferring the modified traits:

The GM wheat and barley lines each contain the *hpt* gene for hygromycin resistance (gene number 36) as well as one of the other 35 genes described in Table 1. Regulatory elements which may be combined with the introduced genes are described in Table 2.

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

Table 1. Name, source and anticipated effect of the introduced genes.

Gene Number	Gene designation [†]	Source organism	Anticipated phenotypic effect of introduced gene or their homologs
H⁺ translocating pyrophosphatase			
1	<i>AtAVP1</i>	<i>A. thaliana</i>	Improved salinity and drought tolerance, and low phosphorus tolerance.
Aminotransferase			
2	<i>Aminotransferase</i>	<i>H. vulgare</i>	Improved nitrogen use efficiency.
TRANSCRIPTION FACTORS			
3	<i>CELLWALL1</i>	CCI	Possible secondary cell wall biosynthesis regulator in vascular tissues, quality of light-dependent regulation of stem length.
4	<i>CELLWALL2</i>	CCI	Unknown. Possibly cell wall and/or chloroplast gene regulator.
5	<i>DROUGHT1</i>	CCI	Drought-inducible, may be involved in drought induced male sterility, may be responsible for chloroplast stability.
6	<i>DROUGHT2</i>	CCI	Drought-inducible, may be involved in drought induced male sterility, may be responsible for chloroplast stability.
7	<i>DROUGHT3</i>	CCI	Drought inducible, may provide a connection between cell expansion and plant turgor, chloroplast stability, protection from pathogens under drought.
8	<i>TaDREB2</i>	<i>T. aestivum</i>	Recovery after drought and no undesirable phenotype in wheat under inducible Rab17 promoter, regulator of drought and cold inducible genes.
9	<i>TaDREB3</i>	<i>T. aestivum</i>	Recovery after drought in wheat under Rab17 promoter, frost tolerance, regulator of drought and cold inducible genes..
10	<i>ZmDREB2</i>	<i>Z. mays</i>	Drought inducible. Expected increase in drought and cold tolerance.
11	<i>DROUGHT4</i>	CCI	Isolated from drought/high temperature library. Expected to be regulator of drought/frost tolerance.
12	<i>COLD1</i>	CCI	Isolated from 'cold'/frost' gene library. No induction by cold, but can activate cold/drought/salt inducible promoter of <i>PROMOTER2</i> (see Table 2).
13	<i>COLD2</i>	CCI	Isolated from 'cold/frost' gene library. Strongly and specifically induced by cold.
14	<i>DROUGHT5</i>	CCI	Drought tolerance (if overexpressed). Stomatal closure, wax.
15	<i>DROUGHT6</i>	CCI	
16	<i>ZmCBF1</i>	<i>Z. mays</i>	Involved in plant cold acclimation; drought, salt, cold and freezing tolerance; pathogen defence; chloroplast development and tolerance to oxidative stress; stunted phenotype.
17	<i>ZmCBF4</i>	<i>Z. mays</i>	
18	<i>DROUGHT7</i>	CCI	Drought inducible, strongly activates <i>PROMOTER2</i> , increase in biotic stress tolerance expected.
19	<i>DROUGHT8</i>	CCI	Binds and strongly activates <i>PROMOTER2</i> , stress inducible, resistance to pathogens also expected.
20	<i>DROUGHT9</i>	CCI	Binds and strongly activates <i>PROMOTER2</i> , stress inducible, resistance to pathogens also expected.
21	<i>DROUGHT10</i>	CCI	Binds and strongly activates <i>PROMOTER2</i> , stress inducible, resistance to pathogens also expected.
22	<i>DROUGHT11</i>	CCI	Drought inducible, homologue of <i>DROUGHT7</i> .
23	<i>DROUGHT12</i>	CCI	Some drought tolerance. Binds and strongly activates <i>PROMOTER2</i> , potential substrate for drought/salt inducible kinases.
24	<i>DROUGHT13</i>	CCI	Improvement of drought tolerance in GM plants, homologue of <i>DROUGHT12</i> , potential substrate of stress inducible kinases
25	<i>DROUGHT14</i>	CCI	Drought/cold inducible
26	<i>DROUGHT15</i>	CCI	Drought inducible
27	<i>COLD3</i>	CCI	From 'cold/frost' gene library, induced during recovery after stress.
PROTEIN KINASES			
28	<i>KINASE1</i>	CCI	Abscisic acid (ABA), drought, salt and cold inducible kinase. May regulate binding of bZip factors to ABA-inducible promoters. GM plants show better recovery after drought stress than control plants
29	<i>KINASE2</i>	CCI	ABA, drought, salt and cold inducible kinase. May regulate binding of bZip factors to ABA-inducible promoters.
30	<i>KINASE3</i>	CCI	Drought inducible kinase.
31	<i>KINASE</i>	CCI	Induced by salt stress. Kinase substrate, isolated from cDNA

Gene Number	Gene designation [†]	Source organism	Anticipated phenotypic effect of introduced gene or their homologs
	<i>SUBSTRATE4</i>		drought stress library.
OTHER PROTEINS			
Zn-regulated transporters			
32	<i>HvZIP7</i>	<i>H. vulgare</i>	Involved in zinc translocation, expected to increase zinc uptake and translocation and increase zinc content of grain.
Na⁺ pumping ATPase			
33	<i>PpENA1</i>	<i>P. patens</i>	Na ⁺ transporter, expected to confer increased salt tolerance.
Calcineurin B-like interacting protein kinase			
34	<i>AtCIPK16</i>	<i>A. thaliana</i>	Protein interacts with calcineurin B-like proteins, upregulated under salt stress.
Na⁺/H⁺ antiporter			
35	<i>ScNHA1</i>	<i>S. cerevisiae</i>	Na ⁺ , K ⁺ /H ⁺ , important for salinity tolerance in yeast, may improve salinity tolerance in plants.
Marker gene (all lines)			
Hygromycin phosphotransferase			
36	<i>Hpt</i>	<i>E.coli</i>	Resistance to the antibiotic hygromycin

[†]Identities of some of the genes have been declared CCI. The applicant has assigned a designation to each of the genes and these are listed in Column 2.

Table 2. Regulatory sequences which may be combined with the introduced genes described in Table 1.

Gene of interest	Promoters [†]	Origin, expression pattern and/or inducibility*	Terminator
<i>Gene 1</i>	2x35S pUbi pRab17	CaMV (Constitutive) Maize (Constitutive) Maize (DI, SI, CI)	nos
<i>Gene 2</i>	OsAnt1	Rice (Root specific)	nos
Transcription Factors			
<i>Genes 3-27</i>	2x35S (transcription factors only) pUbi pRab17 <i>PROMOTER1</i> <i>PROMOTER2</i>	CaMV (Constitutive) Maize (Constitutive) Maize (DI, SI) Barley (DI, SI, CI) Wheat (DI, SI, CI)	nos
Kinase/kinase substrate			
<i>Genes 28-31</i>	<i>PROMOTER3</i> <i>PROMOTER4</i> <i>PROMOTER5</i> <i>PROMOTER6</i> <i>PROMOTER7</i>	Wheat (DI, SI, CI) Wheat (DI, SI, CI) Wheat (DI, CI) Wheat (DI) Wheat (DI)	nos
Other genes			
<i>Gene 32</i>	2x35S	CaMV (Constitutive)	nos
<i>Gene 33</i>	2x35S actin	CaMV (Constitutive) Rice (Constitutive)	nos
<i>Gene 34</i>	2x35S	CaMV (Constitutive)	nos
<i>Gene 35</i>	2x35S	CaMV (Constitutive)	nos

[†]Identities of some of the promoters have been declared CCI. The applicant has designated these promoters *PROMOTER1* – *PROMOTER7*.