



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

# **Licence for dealings involving an intentional release of a GMO into the environment**

**Licence No.: DIR 128**

**Licence holder: The University of Adelaide**

**Title: Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance or micronutrient uptake**

Issued: 4 August 2014  
Varied: 5 January 2015  
Varied 9 December 2016  
Varied 7 May 2018

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

### **Gene Technology Regulation in Australia**

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

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

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

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

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

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

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

Information about where the GMOs have been planted pursuant to this licence can be accessed on the OGTR website on [DIR 128](#) page.

## **Section 1 Interpretations and Definitions**

1. In this licence:

- (a) unless defined otherwise, words and phrases used have the same meaning as they do in the Act and the Gene Technology Regulations 2001;
- (b) words importing a gender include any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing persons include a partnership and a body whether corporate or otherwise;
- (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;
- (f) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;
- (g) specific conditions prevail over standard conditions to the extent of any inconsistency.

2. In this licence:

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

**‘Barley’** means plants of the species *Hordeum vulgare* L.

**‘Break Crops’** means non-GM plants approved in writing by the Regulator.

**‘Buffer Zone’** means an area of land extending outwards at least 2 m from the outer edge of a Planting Area but inside the fence (see Figure 1).

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

- (a) in relation to an area specified in this licence as requiring Cleaning, the Destruction of the GMOs and Plant Material in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs and Plant Material from the Equipment, to the reasonable satisfaction of the Regulator.

**‘Contingency Plan’** means a written plan detailing measures to be taken in the event of the unintended presence of the GMOs or Plant Material outside an area that must be inspected. A Contingency Plan must include procedures to:

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

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

- (a) uprooting;
- (b) Tilling, but only subject to the conditions of this licence;
- (c) treatment with herbicide;

- (d) burning/incineration;
- (e) autoclaving;
- (f) hammer milling; or
- (g) 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, tilling would not be appropriate due to the possible introduction of large numbers of viable seeds into the seedbank.*

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

**'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.

**'Isolation Zone'** means an area of land extending outwards at least 190 m in all directions from the outer edge of the Monitoring Zone (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 OGTR on request.

**'Monitoring Zone'** means an area of land extending either inwards or outwards at least 10 m from the fence (see Figure 1).

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

**'Personal Information'** means information or an opinion (including information forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

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

**'Plant Material'** means any part of the GM or non-GM Wheat and Barley plants grown at a Planting Area, 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, but not including material made non-viable for experimental analysis.

**'Population'** means two or more plants of a specified class per 10 square metres of land.

**'Related Species'** means plants of the species *Hordeum vulgare* and the genus *Triticum*, including *Triticum aestivum* L., but not including the GMOs, other GM *H. vulgare* and GM *T. aestivum* approved in writing by the Regulator for growing at the Site, or non-GM Wheat and Barley plants planted and grown according to this licence.

**'Regulator'** means the Gene Technology Regulator.

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

**‘Site’** means the area of land surrounded by a fence within which one or more Planting Areas and associated Buffer Zones may be established.

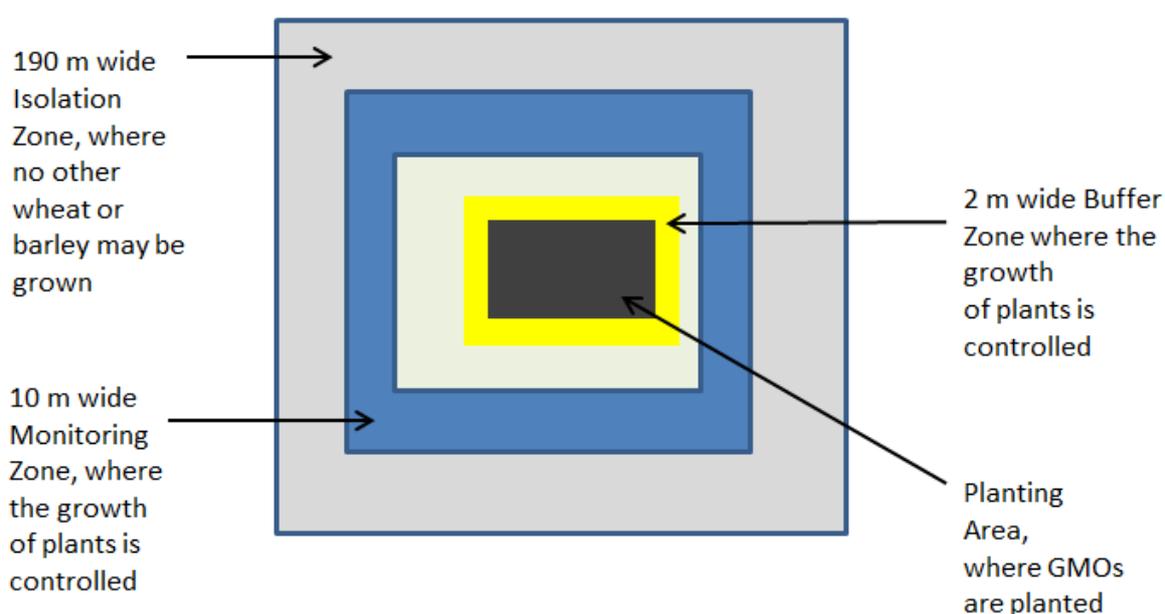
**‘Tillage’** (or **‘Tilled’** or **‘Tilling’**) means the use of any technique to disturb the soil.

**‘Volunteers’** means GM or non-GM Wheat and Barley plants that have not been intentionally grown.

**‘Wash Down Facility’** means an area immediately adjacent to the Sites in Merredin and Katanning, used for cleaning of equipment, with a sealed base and a system for collection of water and waste Plant Material from cleaning.

**‘Waterways’** means all permanent natural waterways and man-made waterways that flow into natural waterways.

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



**Figure 1.** Diagram showing the relationship between a Planting Area, a Buffer Zone, a Monitoring Zone and an Isolation Zone (not drawn to scale).

## **Section 2 General conditions and obligations**

3. This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

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

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

6. The licence holder must notify the Regulator in writing as soon as practically possible if any of the contact details of the project supervisor change from those notified in the licence application or subsequently.

*Note: please address correspondence to [ogtr.applications@health.gov.au](mailto:ogtr.applications@health.gov.au).*

7. The persons covered by this licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise

authorised by the licence holder to undertake any activity in connection with the dealings authorised by this licence.

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

### ***Obligations of the Licence Holder***

*Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following conditions address ongoing suitability of the licence holder.*

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

10. The licence holder must:

- (a) inform the Regulator immediately in writing, of:
  - i. any relevant conviction of the licence holder occurring after the commencement of this licence; and
  - ii. any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment; and
  - iii. any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it; and
- (b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested, within the stipulated timeframe.

11. The licence holder must be able to access and control all Planting Areas, Monitoring Zones, Isolation Zones and approved facilities to the extent necessary to comply with this licence, for the duration of the life of the licence.

*The following conditions seek to ensure that persons conducting the dealings are aware of the licence conditions and appropriate processes are in place to inform people of their obligations.*

12. Prior to conducting any dealings with the GMOs, the licence holder must provide to the Regulator:

- (a) names of all organisations and persons or functions or positions of the persons who will be covered by the licence, with a description of their responsibilities; and  
*Note: Examples of functions or positions are 'Site manager', 'Farm labourer', 'Courier' etc.*
- (b) detail of how the persons covered by the licence will be informed of licence conditions; and
- (c) detail of how the Licence Holder will access and control all Planting Areas, Monitoring Zones, Isolation Zones and approved facilities for the duration of the licence; and  
*Note: this may include a description of any contracts, agreements, or other enforceable arrangements.*
- (d) written methodology to reliably detect the GMOs, the genetic modifications and distinguish between categories of the GMOs; and

- (e) a Contingency Plan to respond to inadvertent presence of the GMOs outside an area that must be inspected.
13. Any changes to the information provided under the immediately preceding condition must be communicated in writing to the Regulator within 14 days of the changes occurring.
14. The licence holder must inform any person covered by this licence, to whom a particular condition of the licence applies, of the following:
- (a) the particular condition (including any variations of it); and
  - (b) the cancellation or suspension of the licence; and
  - (c) the surrender of the licence.
15. The licence holder must not permit a person covered by this licence to conduct any dealing unless:
- (a) the person has been informed of any applicable licence conditions, including any variation of them; and
  - (b) the licence holder has obtained from the person a signed and dated statement that the person:
    - i. has been informed by the licence holder of the licence conditions, including any variation of them; and
    - ii. has understood and agreed to be bound by the licence conditions, or variation.
16. The licence holder must:
- (a) inform the persons covered by this licence that any Personal Information relevant to the administration and/or enforcement of the licence may be released to the Regulator; and
  - (b) provide the Regulator, if requested, with copies of the signed and dated statements referred to in the immediately preceding condition.

### ***Provision of new information to the Regulator***

*Licence conditions are based on the risk assessment and risk management plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment is communicated to the Regulator.*

17. The licence holder must inform the Regulator if the licence holder becomes aware of:
- (a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or
  - (b) any contraventions of the licence by a person covered by the licence; or
  - (c) any unintended effects of the dealings authorised by the licence.

*Note: The Act requires, for the purposes of the above condition, that:*

- (a) *the licence holder will be taken to have become aware of additional information of a kind mentioned in paragraph 17(a) if he or she was reckless as to whether such information existed; and*
- (b) *the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in paragraph 17(b) if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

*Note: Contraventions of the licence may occur through the action or inaction of a person. For example if it is a condition of the licence that volunteers are destroyed prior to reaching maturity and a volunteer reaches maturity, then the person responsible for controlling volunteers will have contravened that licence condition.*

18. If the licence holder is required to inform the Regulator under the immediately preceding condition, the Regulator must be informed without delay.

*Note: An example of informing without delay is contact made at the time of the incident via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location if required.*

19. If the licence holder informs the Regulator under the immediately preceding condition and the Regulator requests further information, the further information must be provided in a manner, and within the time period, stipulated by the Regulator.

### ***Obligations of persons covered by the licence***

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

21. If a person is authorised by this licence to deal with the GMOs and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

## **Section 3 Limits and control measures**

### ***Limits on the release***

*The following licence conditions maintain the risk assessment context within which the application was assessed, by imposing limits on where and when the GMOs may be grown, and on other activities that can be undertaken.*

22. The only plants that may be intentionally grown in a Planting Area are:

- (a) the GMOs covered by this licence as described in the Attachment A of the licence; and
- (b) plants approved in writing by the Regulator; and
- (c) non-GM Wheat and Barley plants.

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

| Local government area | Location   | Maximum number of Sites established per season | Maximum cumulative size of Planting Areas per Site | Duration                               |
|-----------------------|--|--|--|--|
| Marion, SA            | O'Halloran Hill                                    | 1  | 0.5 ha   | August 2014 – December 2019, inclusive |
| Corrigin, WA          | Kunjin, near Corrigin                              | 1  | 0.5 ha   | August 2014 – December 2019, inclusive |
| Merredin, WA          | New Genes for New Environments facility, Merredin  | 1  | 2.0 ha   | August 2014 – December 2019, inclusive |
| Katanning, WA         | New Genes for New Environments facility, Katanning | 1  | 2.0 ha   | August 2014 – December 2019, inclusive |

24. Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals.

25. If GM plants, other than the GMOs authorised by this licence or those that satisfy condition 22 (b), are:

- (a) grown under another licence within the Site at a time when the GMOs authorised by this licence are also being grown; and
- (b) sexually compatible with the GMOs authorised by this licence;

then seed produced from the GMOs grown under this licence at the Site must not be used in the future development of cultivars for commercial release.

26. If experimentation or storage of the Plant Material is not conducted in accordance with Notifiable Low Risk Dealings (NLRD) requirements, then such activities may only be undertaken within:

- (a) a Planting Area; or
- (b) a facility approved in writing by the Regulator.

*Note: Dealings conducted in accordance with NLRD requirements must be assessed by an IBC before commencement, must comply with the requirements of the Gene Technology Regulations 2001, and are not subject to the conditions of this licence.*

### **Containment measures**

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

### **Pollen and seed dispersal during cultivation**

- 27. The outer edge of the Planting Area must be at least 50m away from Waterways.
- 28. The outer edge of the Planting Area must be surrounded by a Buffer Zone. The Buffer zone must not overlap with a Buffer Zone authorised by another licence issued by the Regulator.
- 29. The Site must be surrounded by a fence.
- 30. A Monitoring Zone should extend either inwards or outwards from the fence.

31. The Monitoring Zone, or the fence if the Monitoring Zone is inside the fence, must be surrounded by an Isolation Zone. In the Isolation Zone no wheat or barley may be grown.
32. The fence must be capable of excluding livestock and have lockable gates that must be locked except when accessed by authorised persons.
33. The only plants permitted to be purposely grown within the Site, but outside a Planting Area and its Buffer Zone, are Break Crops or plants authorised by another licence issued by the Regulator.
34. Only Break Crops may be grown in a Buffer Zone.
35. Material collected from Break Crops must be Destroyed.
36. While the GMOs are growing in a Planting Area, associated areas must be inspected by people trained to recognize Wheat, Barley and Related Species, and actions taken, as follows:

| Area                                      | Period of inspection   | Inspection frequency        | Inspect for                  | Action  |
|---|--|-----------------------------|------------------------------|---|
| (a) Planting Area                         | <b>From</b> 14 days prior to the expected commencement of Flowering of any GMOs*<br><br><b>until</b> all Wheat and Barley in the Planting Area has been Harvested or Destroyed | At least once every 14 days | Related Species              | Destroy before Flowering or prevent from Flowering  |
| (b) Buffer Zone & other areas in the Site | <b>From</b> 14 days prior to the expected commencement of Flowering of any GMOs*<br><br><b>until</b> all Wheat and Barley in the Planting Area has been Harvested or Destroyed | At least once every 14 days | Volunteers & Related Species | Destroy before Flowering or prevent from Flowering  |
| (c) Monitoring zone                       |  |                             |                              |   |
| (d) Isolation Zone                        | <b>From</b> 14 days prior to the expected commencement of Flowering of any GMOs*<br><br><b>until</b> all GMOs in the Planting Area have finished Flowering                     | At least once every 14 days | Volunteers & Related Species | Destroy before Flowering or prevent from Flowering, such that no Population of Related Species Flower |
| (e) Fence                                 | While the GMOs are growing   | At least once every 14 days | Damage                       | Repair as soon as possible to maintain exclusion of livestock from the Site                           |

*\*Condition 55(a) requires the licence holder to provide information to the Regulator on the expected flowering period, however the inspection period should be based on the observed development of the GMOs, so that inspections commence prior to flowering of any GMOs.*

*Note: Details of any inspection activity must be recorded in a Logbook as detailed in Condition 51.*

### **Dispersal of Plant Material**

37. The Monitoring Zone must be maintained in a manner that does not attract or harbour rodents while the GMOs are being grown at a Planting Area and until the Planting Area and associated Buffer Zone are Cleaned.

*Note: Measures to achieve this could include areas of land free of any vegetation and/or vegetation kept mown to a height of less than 10 centimetres and/or baiting.*

38. Measures must be implemented to control rodents within the Planting Area while GMOs are being grown and until the Planting Area and associated Buffer Zone have been Cleaned.

*Note: Measures for rodent control may include, but are not limited to, traps and/or poison bait within and/or surrounding the Planting Area and associated Buffer Zone.*

39. Non-GM Wheat and Barley grown in a Planting Area must be handled as if they were the GMOs.

40. Plant Material must be harvested separately from any other crop.

41. If the GMOs or Plant Material from a Planting Area are harvested, they must be harvested by hand, a mechanical single-row harvester, or a small plot harvester.

*Note: For the purpose of this licence, harvested by hand refers to the cutting of plant stems using an implement such as a hand sickle or secateurs.*

42. Harvesting must be conducted in a manner so as to avoid dispersal of Plant Material outside the Planting Area and associated Buffer Zone.

43. 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.

44. If seed harvested from the GMOs or Plant Material is threshed other than in accordance with NLRD requirements, it must be threshed separately from any other crop, and threshing must take place on the Planting Areas or in a facility approved in writing by the Regulator.

45. Areas of land and equipment used in connection with the GMOs must be Cleaned as follows:

| Areas/Equipment to be Cleaned  | When   |
|--|--|
| (a) Planting Area and Buffer Zone  | Before the end of the first May following harvesting of the GMOs |
| (b) any area where Plant Material has dispersed during planting, growing or harvesting | As soon as practicable and before use for any other purpose      |
| (c) any area used to Clean any equipment used in connection with the GMOs              |  |
| (d) any area used to Destroy any Plant Material  |  |
| (e) any area used to store or experiment with Plant Material                           |  |
| (f) any equipment used in connection with the GMOs                                     |  |
|  |  |

*Notes: If tillage is used as a means of Cleaning, it must be conducted in accordance with Condition 52. Areas of land that have been cleaned, or from which the GMOs have been harvested, are also subject to Inspections (Condition 50). Cleaning activities must be recorded and provided to the Regulator (Condition 55(d)).*

46. Any extreme weather event that is expected to affect or has already affected a Site, while the GMOs are growing or while the Site is subject to inspection requirements, must be notified in writing to the Regulator as soon as practically and reasonably possible.

*Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 53).*

**Dispersal of the GMOs during transport or storage**

47. If transport or storage is not conducted in accordance with NLRD requirements, it must be conducted in accordance with conditions 48 and 49.

*Note: Dealings conducted in accordance with NLRD requirements must be assessed by an IBC before commencement, must comply with the requirements of the Gene Technology Regulations 2001 and are not subject to conditions of this licence.*

48. Transport and storage of Plant Material must:

- (a) only occur to the extent necessary to conduct the dealings permitted by this licence; and
- (b) be in accordance with the Regulator’s *Guidelines for the Transport, Storage and Disposal of GMOs* for PC2 GM plants as current at the time of transportation or storage; and
- (c) comply with all other conditions of this licence.

*Note: Condition 15 requires signed statements for persons transporting or disposing of the GMOs.*

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

**Persistence of the GMOs or GM Volunteers post-harvest or post Cleaning**

50. Areas of land, excluding a Wash-Down facility, must be inspected by people trained to recognise Wheat and Barley and actions taken as follows:

| Area of land   | Period of inspection  | Inspection frequency  | Inspect for | Action  |
|--|---|---|-------------|---|
| (a) Planting Areas and associated Buffer zones                             | From the day of completion of the harvest or destruction of the last Wheat and Barley in the Planting Area, until: <ul style="list-style-type: none"> <li>i. the area is replanted with the GMO; or</li> <li>ii. the Regulator has issued a Sign-off for the area.</li> </ul> | At least once every 35 days   | Volunteers  | Destroy before Flowering  |
| (b) Areas that have been Cleaned (excluding Planting Area and Buffer Zone) | From the day of Cleaning, until: <ul style="list-style-type: none"> <li>i. the area is replanted with the GMO; or</li> <li>ii. the Regulator has issued a Sign-off for the area.</li> </ul>   |   |             |   |
| (c) Fence  | From the day of completion of the harvest or destruction of the last Wheat and Barley in the Planting Area, and when livestock are being grazed outside but adjacent to the fence   | Each time upon the introduction of livestock and thereafter at least once every 35 days | Damage      | Repair as soon as possible to maintain exclusion of livestock from the Site |

| Area of land  | Period of inspection  | Inspection frequency        | Inspect for | Action                   |
|---|---|-----------------------------|-------------|--------------------------|
| (d) Areas in a Site transferred from licence DIR 102 that were subject to post-harvest or post-Cleaning monitoring* | From the day of transfer, until: <ul style="list-style-type: none"> <li>i. the area is replanted with the GMO; or</li> <li>ii. the Regulator has issued a Sign-off for the area.</li> </ul> | At least once every 35 days | Volunteers  | Destroy before Flowering |

*\*Note: These areas were defined as a Place under DIR 102 licence and are now authorised under DIR 128 licence once approved in writing by the Regulator.*

51. Details of any inspection activity must be recorded in a Logbook and must include:

- (a) date of the inspections;
- (b) name of the person(s) conducting the inspection;
- (c) details of the experience, training or qualification that enables the person(s) to recognise Wheat and Barley Volunteers and Related Species, if not already recorded in the logbook;
- (d) details of areas inspected including current land use (including details of any post-harvest crops), and recent management practices applied (including tillage events);  
*Note: this may also include spraying or maintenance measures used to facilitate inspections for Volunteers/Related Species*
- (e) details of any post-harvest rainfall events including measurements at or near the area, or any irrigation events;
- (f) details of any post-harvest Volunteers observed including number, developmental stage and approximate position of the Volunteers with each area inspected\*;
- (g) details of any damage and any repairs to the fence surrounding the Site;
- (h) date(s) and method(s) of Destruction or preventing flowering of any Volunteers; and
- (i) details of rodent control methods used any evidence of rodent activity.

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

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

*Note: Details of Inspection activities must be provided to the Regulator (Condition 55(e)).*

52. While post-harvest or post-Cleaning inspection requirements apply to an area:

- (a) the area must be maintained in a manner appropriate to allow identification of Volunteers; and
- (b) any Tillage of the area must be to a depth no greater than the depth of sowing of the GMOs; and

*Note: delaying the first for at least 28 days following the harvest of the GMOs may promote after-ripening of grain remaining on the soil surface and thereby reduce persistence of seed in the soil, however if conditions are conducive to germination Tillage may be carried out earlier.*

- (c) no plants may be intentionally grown in the area unless:
  - i. the plants are the GMOs or non-GM Wheat and Barley planted in accordance with the conditions of this licence; or
  - ii. written approval is given by the Regulator for the plants to be grown in the area; and
- (d) prior to an application for Sign-off, the area must receive at least three irrigations, at intervals of at least 28 days, with the last required irrigation occurring at a time that would promote the germination of Volunteers within the six month period immediately prior to the Sign-off application; and

*Note: A period of natural rainfall may be taken as irrigation only with the agreement of the Regulator. Evidence (such as rainfall measurements, photos etc.) that the rainfall has been sufficient to promote germination should be provided.*

- (e) prior to the final irrigation referred to in the immediately preceding condition, the area must be Tilled.

### ***Contingency plan***

53. If any unintentional presence of the GMOs or plant material from the GMOs is detected outside the areas requiring inspection, the Contingency Plan must be implemented.

## **Section 4 Sign off**

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

- (a) all post-harvest or post-Cleaning inspection activities have been conducted for at least 24 months on the area and all associated areas of land; and
- (b) no Volunteers have occurred on these areas in the most recent six month inspection period.

*Note: Associated areas refers to a Planting Area and the aggregate of all other areas of land requiring post-Cleaning inspections in respect of that Planting Area. Associated areas will be signed-off as a group rather than individually. Licence conditions require at least one tillage and three irrigations or rainfall events for each area prior to Sign-off application. The Regulator will take into account the management and inspection history for all associated areas, including tillage and irrigation regimes and management of any occurrence of Volunteers, in deciding whether or not he is satisfied that no further inspections are required to manage persistence of the GMOs.*

## **Section 5 Reporting and Documentation**

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

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

| Notice                    | Content of notice  | Timeframe   |
|---------------------------|--|---|
| (a) Intention to Plant    | <ul style="list-style-type: none"> <li>i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the site (eg google maps) and any other directions</li> <li>ii. Identity of the GMOs to be planted at the Planting Area (eg lines or construct details)</li> <li>iii. Date on which the GMOs will be planted</li> <li>iv. Period when the GMOs are expected to Flower</li> <li>v. Period when harvesting is expected to commence</li> <li>vi. If GMOs have previously been planted at the Planting Area, a history indicating how the Planting Area has been used in the preceding 2 years, including details of previous GMOs and post-harvest crops planted</li> <li>vii. How the Planting Area is intended to be used during first two years following harvest</li> </ul> | At least 7 days prior to each planting (to be updated immediately if the notified details change) |
| (b) Planting              | <ul style="list-style-type: none"> <li>i. Actual date(s) of planting the GMOs</li> <li>ii. Any changes to the details provided under 55(a)</li> </ul>  | Within 7 days of any planting   |
| (c) Harvest               | <ul style="list-style-type: none"> <li>i. Actual date(s) of harvesting the GMOs</li> </ul>   | Within 7 days of commencement of any Harvesting   |
| (d) Cleaning              | <ul style="list-style-type: none"> <li>i. Actual date(s) on which any areas needing Cleaning were Cleaned</li> <li>ii. Method of Cleaning</li> </ul>   | Within 7 days of completion of any Cleaning   |
| (e) Inspection activities | <ul style="list-style-type: none"> <li>i. Information recorded in a Logbook as per the inspection requirement tables</li> </ul>  | Within 35 days of Inspection  |

*Note: Other reports and documents that may need to be sent to the Regulator are described under Conditions 10(a), 10(b), 17 and 46. A check list of documents that are required to be sent to the Regulator is provided at Attachment B of the licence.*

**DIR No: 128**

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

**Organisation Details**

Postal address: The University of Adelaide  
South Australia 5005  
Australia  
Phone No: (08) 8313 4455

**IBC Details**

IBC Name: The University of Adelaide Institutional Biosafety Committee

**GMO Description**

**GMOs covered by this licence:**

*Triticum aestivum* L. and *Hordeum vulgare* L. containing only the introduced genes and regulatory elements as described in Tables 1, 2, 3 and 4.

Additionally, other GM wheat and barley plants approved under Licence DIR 102 may also be dealt with under this licence if they occur as Volunteers but may not be intentionally planted.

**Parent Organisms:**

Common Names: Wheat and Barley

Scientific Names: *Triticum aestivum* L. and *Hordeum vulgare* L.

**Modified traits:**

Categories: Abiotic stress tolerance  
Micronutrient uptake  
Selectable markers

Description: Wheat and barley plants have been genetically modified for enhanced abiotic stress tolerance or micronutrient uptake.

**Genetic elements responsible for conferring the modified trait:**

The GM wheat and barley lines each contain one of 33 genes of interest, and either or both of the two selectable marker genes *nptII* and *hptII*. The genes are described in Table 1, promoters in Table 2, genomic elements in Table 3 and terminators in Table 4. Details of the genes and regulatory elements inserted into many of the GM wheat and barley lines have been declared Confidential Commercial Information (CCI) under section 185 of the Act.

**Purpose of the dealings with the GMOs:**

The University of Adelaide applied for a licence for dealings involving the intentional release of GM wheat and barley lines on a limited scale and under controlled conditions.

The primary purpose of the field trial is to assess whether the introduction and expression of the specified groups of genes in plants affects yield potential under field conditions. GM material generated from this field trial will not be used in human food or animal feed.

GMOs authorised under this licence may be planted on Sites previously planted under DIR 102 licence. Therefore, volunteers of GM wheat and barley plants approved under Licence DIR 102 may be present at these Sites.

**Table 1. Name and source of introduced genes.**

| Gene of interest and source organism <sup>#</sup>     | Plants transformed                |
|---|-----------------------------------|
| <i>SIGNALLING PROTEIN 2</i>                           | <i>T. aestivum</i>                |
| <i>TRANSCRIPTION FACTOR 1</i>                         | <i>T. aestivum</i>                |
| <i>TRANSCRIPTION FACTOR 3</i>                         | <i>T. aestivum</i>                |
| <i>TRANSCRIPTION FACTOR 4</i>                         | <i>T. aestivum</i>                |
| <i>TRANSCRIPTION FACTOR 5</i>                         | <i>T. aestivum</i>                |
| <i>TRANSCRIPTION FACTOR 6</i>                         | <i>T. aestivum and H. vulgare</i> |
| <i>TRANSCRIPTION FACTOR 7</i>                         | <i>T. aestivum</i>                |
| <i>TRANSCRIPTION FACTOR 9</i>                         | <i>T. aestivum</i>                |
| <i>PHOTOSYNTHESIS AND METABOLISM GENE 3</i>           | <i>T. aestivum</i>                |
| <i>PHOTOSYNTHESIS AND METABOLISM GENE 4</i>           | <i>T. aestivum</i>                |
| <i>PHOTOSYNTHESIS AND METABOLISM GENE 5</i>           | <i>T. aestivum</i>                |
| CELL SPECIFICATION, PROLIFERATION AND DIVISION GENE 2 | <i>T. aestivum</i>                |
| CELL SPECIFICATION, PROLIFERATION AND DIVISION GENE 3 | <i>T. aestivum</i>                |
| RNA METABOLISM PROCESSING GENE 1                      | <i>H. vulgare</i>                 |
| RNA METABOLISM PROCESSING GENE 2                      | <i>H. vulgare</i>                 |
| RNA METABOLISM PROCESSING GENE 3                      | <i>T. aestivum and H. vulgare</i> |
| RNA METABOLISM PROCESSING GENE 4                      | <i>T. aestivum and H. vulgare</i> |
| <i>ScNHA1 (Saccharomyces cerevisiae)</i>              | <i>T. aestivum and H. vulgare</i> |
| <i>PpENA1 (Physcomitrella patens)</i>                 | <i>T. aestivum and H. vulgare</i> |
| <i>AtAVP (A. thaliana)</i>                            | <i>T. aestivum and H. vulgare</i> |
| <i>AtCIPK16 (A. thaliana)</i>                         | <i>T. aestivum and H. vulgare</i> |
| <i>OshKT1;5 (Oryza sativa)</i>                        | <i>T. aestivum</i>                |
| <i>TaALMT1 (T. aestivum)</i>                          | <i>T. aestivum and H. vulgare</i> |
| <i>TaALMT1_minus_insert (T. aestivum)</i>             | <i>H. vulgare</i>                 |
| <i>ION TRANSPORTER 5</i>                              | <i>T. aestivum and H. vulgare</i> |
| <i>ION TRANSPORTER 6</i>                              | <i>T. aestivum and H. vulgare</i> |
| <i>ION TRANSPORTER 7C</i>                             | <i>T. aestivum and H. vulgare</i> |
| <i>ScALMT1.M39.1_wt (Secale cereale)</i>              | <i>T. aestivum and H. vulgare</i> |
| <i>ScALMT1.M39.1_plus insert (Secale cereale)</i>     | <i>H. vulgare</i>                 |
| <i>HvAACT1 (H. vulgare)</i>                           | <i>T. aestivum and H. vulgare</i> |
| <i>TRANSCRIPTION FACTOR 2</i>                         | <i>T. aestivum</i>                |
| <i>TRANSCRIPTION FACTOR 8</i>                         | <i>T. aestivum</i>                |
| <i>AMINOTRANSFERASE</i>                               | <i>T. aestivum and H. vulgare</i> |
| CELL SPECIFICATION, PROLIFERATION AND DIVISION GENE 1 | <i>T. aestivum</i>                |
| <i>OsNAS2 (Oryza sativa)</i>                          | <i>T. aestivum</i>                |

<sup>#</sup> Those genes of interest for which CCI has been declared have been assigned a designation by the applicant.

**Table 2. Promoters used in constructs.**

| Name of promoter <sup>#</sup> | Name of gene from which promoter derived <sup>#</sup> | Source organism                 |
|-------------------------------|---|---------------------------------|
| <i>CaMV35S</i>                | <i>Viral promoter</i>                                 | <i>Cauliflower mosaic virus</i> |
| <i>pAct</i>                   | <i>OsAct</i>  | <i>O. sativa</i>                |
| <i>pAtCIPK16</i>              | <i>AtCIPK16</i>                                       | <i>A. thaliana</i>              |
| <i>pAtPHT1;1</i>              | <i>AtPHT1;1</i>                                       | <i>A. thaliana</i>              |
| <i>pAtPOT2</i>                | <i>AtPOT2</i>   | <i>A. thaliana</i>              |
| <i>pB4L</i>                   | <i>TdHDZipl-4</i>                                     | <i>T. durum</i>                 |
| <i>pB7L</i>                   | <i>TdHDZipl-3</i>                                     | <i>T. durum</i>                 |
| <i>pCor39</i>                 | <i>TdCor39</i>  | <i>T. durum</i>                 |
| <i>pCor410b</i>               | <i>TdCor410b</i>                                      | <i>T. durum</i>                 |
| <i>pCor410H1(truncated)</i>   | <i>TdCor410H1</i>                                     | <i>T. durum</i>                 |
| <i>pCor410H2 (truncated)</i>  | <i>TdCor410H2</i>                                     | <i>T. durum</i>                 |
| <i>PROMOTER 1</i>             | <i>GENE A</i>   | <i>T. durum</i>                 |
| <i>pDHN8</i>                  | <i>HvDHN8</i>   | <i>H. vulgare</i>               |
| <i>PROMOTER 2</i>             | <i>GENE B</i>   | <i>T. durum</i>                 |
| <i>PROMOTER 3</i>             | <i>GENE C</i>   | <i>T. durum</i>                 |
| <i>PROMOTER 4</i>             | <i>GENE D</i>   | <i>T. durum</i>                 |
| <i>PROMOTER 5</i>             | <i>GENE E</i>   | <i>O. sativa</i>                |
| <i>PROMOTER 6</i>             | <i>GENE F</i>   | <i>O. sativa</i>                |
| <i>PROMOTER 7</i>             | <i>GENE G</i>   | <i>O. sativa</i>                |
| <i>pOsAnt1</i>                | <i>Aldehyde dehydrogenase se1</i>                     | <i>O. sativa</i>                |
| <i>pOsKOR1</i>                | <i>OsKOR1</i>   | <i>O. sativa</i>                |
| <i>PROMOTER 8</i>             | <i>GENE H</i>   | <i>Z. mays</i>                  |
| <i>PROMOTER 9</i>             | <i>GENE I</i>   | <i>T. durum</i>                 |
| <i>pUbi</i>                   | <i>Polyubiquitin</i>                                  | <i>Z. mays</i>                  |
| <i>PROMOTER 10</i>            | <i>GENE J</i>   | <i>T. durum</i>                 |
| <i>pWRKY71 (pJRCO189)</i>     | <i>OsWRKY71</i>                                       | <i>O. sativa</i>                |
| <i>PROMOTER 11</i>            | <i>GENE K</i>   | <i>T. durum</i>                 |
| <i>PROMOTER 12</i>            | <i>GENE L</i>   | <i>Z. mays</i>                  |

<sup>#</sup> The identities of some of the promoters and the genes from which they are sourced have been declared CCI. The applicant has assigned a designation to each of these promoters and genes.

**Table 3. Genomic elements used in constructs.**

| Name of genomic element <sup>#</sup> | Description <sup>#</sup>                 | Source organism <sup>#</sup> |
|--------------------------------------|--|------------------------------|
| <i>Act intron (MOD1)</i>             | <i>intron</i>                            | <i>O. sativa</i>             |
| APS                                  | <i>amplification promoting sequences</i> | <i>N. tabacum</i>            |
| Mini ALLSTOPS                        | <i>Stop codon</i>                        | -                            |
| <i>STLS1 intron 2</i>                | <i>intron</i>                            | <i>S. tuberosum</i>          |
| <i>Ubi intron</i>                    | <i>intron</i>                            | <i>Z. mays</i>               |
| <i>Ubi1 5'UTR</i>                    | <i>5' untranslated region</i>            | <i>Z. mays</i>               |
| UNTRANSLATED SEQUENCE 1              | GENE M                                   | CCI                          |
| <i>Ubi1 intron</i>                   | <i>intron</i>                            | <i>Z. mays</i>               |
| UNTRANSLATED SEQUENCE 2              | GENE N                                   | CCI                          |

<sup>#</sup> The identities of some of the genomic elements, the genes from which they are sourced and the source organisms have been declared CCI. The applicant has assigned a designation to each of these genomic elements and genes.

**Table 4. Terminators used in constructs.**

| Name of terminator <sup>#</sup> | Description <sup>#</sup>                 | Source organism <sup>#</sup>    |
|---------------------------------|--|---------------------------------|
| <i>35S ter</i>                  | <i>Viral terminator</i>                  | <i>Cauliflower mosaic virus</i> |
| TERMINATOR SEQUENCE 1           | <i>Terminator of the GENE A gene</i>     | <i>T. durum</i>                 |
| TERMINATOR SEQUENCE 2           | <i>Terminator of the GENE B gene</i>     | <i>T. durum</i>                 |
| TERMINATOR SEQUENCE 3           | <i>Terminator of the GENE O gene</i>     | CCI                             |
| TERMINATOR SEQUENCE 4           | <i>Terminator of the GENE P gene</i>     | <i>T. durum</i>                 |
| <i>Nos ter</i>                  | <i>Nopaline synthase gene terminator</i> | <i>A. tumefaciens</i>           |
| <i>OsUBI ter</i>                | <i>Polyubiquitin gene terminator</i>     | <i>O. sativa</i>                |
| TERMINATOR SEQUENCE 5           | <i>Terminator of the GENE Q gene</i>     | CCI                             |
| TERMINATOR SEQUENCE 6           | <i>Terminator of the GENE R gene</i>     | CCI                             |
| TERMINATOR SEQUENCE 7           | <i>Terminator of the GENE S gene</i>     | CCI                             |
| TERMINATOR SEQUENCE 8           | <i>Terminator of the GENE T gene</i>     | <i>S. bicolor</i>               |
| TERMINATOR SEQUENCE 9           | <i>Terminator of the GENE U gene</i>     | <i>A. tumefaciens</i>           |

<sup>#</sup> The identities of some of the terminators, the genes from which they are sourced and the source organisms have been declared CCI. The applicant has assigned a designation to each of these terminators and genes.

## ATTACHMENT B

### Checklist of documents that must be sent to the Regulator:

| When                                | What   | Condition | Timeframe   |
|-------------------------------------|--|-----------|---|
| Prior to conducting any dealings    | Details of organisations and persons covered   | 12(a)     |   |
|                                     | Plan to inform people covered by the licence   | 12(b)     |   |
|                                     | Plan to ensure control and access to all the Sites   | 12(c)     |   |
|                                     | Detection methodology  | 12(d)     |   |
|                                     | Contingency plan   | 12(e)     |   |
| Prior to planting                   | Intention to plant   | 55(a)     | At least 7 days prior to any planting                                 |
| During growing                      | Planting   | 55(b)     | Within 7 days of any planting   |
|                                     | Harvest  | 55(c)     | Within 7 days of commencement   |
| Post-Cleaning                       | Cleaning   | 55(d)     | Within 7 days of completion   |
|                                     | Inspection   | 55(e)     | Within 35 days of each inspection                                     |
| Any time after issue of the licence | Any changes of the project supervisor contact details  | 6         | As soon as practically possible                                       |
|                                     | Any relevant conviction, revocation, suspension or cancellation of any relevant permit or circumstances that may affect compliance to licence conditions                                     | 10(a)     | Immediately, if occurs  |
|                                     | Any information relevant to on-going suitability   | 10(b)     | If and when requested   |
|                                     | Any changes to details provided under Conditions 12(a) - 12(e)   | 13        | Within 14 days of the changes   |
|                                     | Signed statements from persons covered under the licence   | 15 (b)    | If and when requested   |
|                                     | Any additional information regarding health and safety of the people and the environment, contraventions of this licence or any unintended effects of the dealings authorised by the licence | 17        | As soon as practically and reasonably possible, after becoming aware  |
|                                     | Extreme weather conditions   | 46        | As soon as practically and reasonably possible, if expected or occurs |
|                                     | Methods and procedures for transport   | 49        | If and when requested   |