



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 112

Licence holder: Commonwealth Scientific and Industrial Research Organisation

Title: Limited and controlled release of wheat and barley genetically modified for altered grain composition and nutrient utilisation efficiency

Issued: 21 March 2012
Surrendered 4 March 2016

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, 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](#).

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.

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

'Break Crop plants' means plants of the species field peas, chickpeas or lentils, or other 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 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:

- (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 (eg bags, containers, trucks), the Wash Down Facility, 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 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.

'Location' means an area of land where the GMOs are intentionally planted and grown (see Figure 1). The area ceases to be a Location once the area is Cleaned.

'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 inwards at least 10 m from the fence.

'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 is required to be, or which has been, Cleaned, and on which the GMOs have not been replanted.

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

'Population' means two 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 barely plants planted and grown according to this licence.

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

'Site' means the area of land surrounded by the Monitoring Zone, within which one or more Locations may be established.

'Tillage' means the use of any technique to disturb the soil.

'Volunteers' means GM or non-GM Wheat (*T aestivum* L.) and Barley (*H. vulgare* L) plants, which have not been intentionally grown.

'Waterways' means all permanent natural waterways and man-made waterways that flow into permanent natural waterways.

'Wash Down Facility' means an area immediately adjacent to the Site, used for cleaning of equipment, with a sealed base and a system for collection of water and waste Plant Material from cleaning.

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

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 Commonwealth Scientific and Industrial Research Organisation.

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 the Regulator with 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 14 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, as soon as practically and reasonably possible, 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. 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.

21. 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

22. 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.

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

24. Prior to growing the GMOs, the licence holder must provide to the Regulator a description of how any contracts, agreements, or other enforceable arrangements will allow the licence holder to access and control the Site, approved facility or other premise to the extent necessary to comply with this licence, for the duration of the life of the licence.

25. Where any of the details provided under the immediately preceding condition change, the licence holder must notify the Regulator of the changes within 14 days of the change occurring.

Growing the GMOs

GMOs covered by this licence

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

Permitted dealings

27. The permitted dealings with the GMOs are to conduct experiments with the GMOs, import, 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.

Plants that may be grown at a Location and Buffer Zone

28. The only plants permitted to be purposely grown at a Location are:

- (a) the GMOs
- (b) non-GM wheat and barley plants

29. Only Break Crop Plants may be grown in a Buffer Zone.

Plants that may be grown within the Site, but outside a Location and Buffer Zone

30. The only plants permitted to be purposely grown within the Site, but outside a Location and its Buffer Zone, are Break Crop Plants or plants authorised by another licence issued by the Regulator.

31. Material collected from Break Crop plants must be Destroyed.

Limits - Location, timing and size of trial

32. With respect to the permitted dealings described in condition 27, planting, propagating, growing and harvesting must only be undertaken between May 2012 and May 2015, inclusive, at one Site, the Department of Agriculture and Food, Western Australia's New Genes for New Environments (NGNE) facility at Merredin, Western Australia.

33. The maximum combined area of all Locations in any growing season must not exceed 1.0 hectare. Intentional planting and growing of the GMOs may occur at multiple Locations within the Site.

Containment measures

34. The fence surrounding the Site must be capable of excluding livestock and have lockable gates that must be locked except when accessed by authorised persons.

35. Each Location must be surrounded by a Buffer Zone.

36. The Site must be surrounded by a Monitoring Zone, the latter extending inwards from the fence.

37. The Monitoring Zone must be surrounded by 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 all Locations in the Site are Cleaned.

39. If rodent activity is detected in the Site, measures must be implemented to control rodents within the Site while GMOs are being grown and until each Place has been Cleaned. These may include, but are not limited to, traps and/or poison bait within and/or surrounding the Site.

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.

40. Any steps taken to control rodents and any evidence of rodent activity must be recorded in a Logbook.

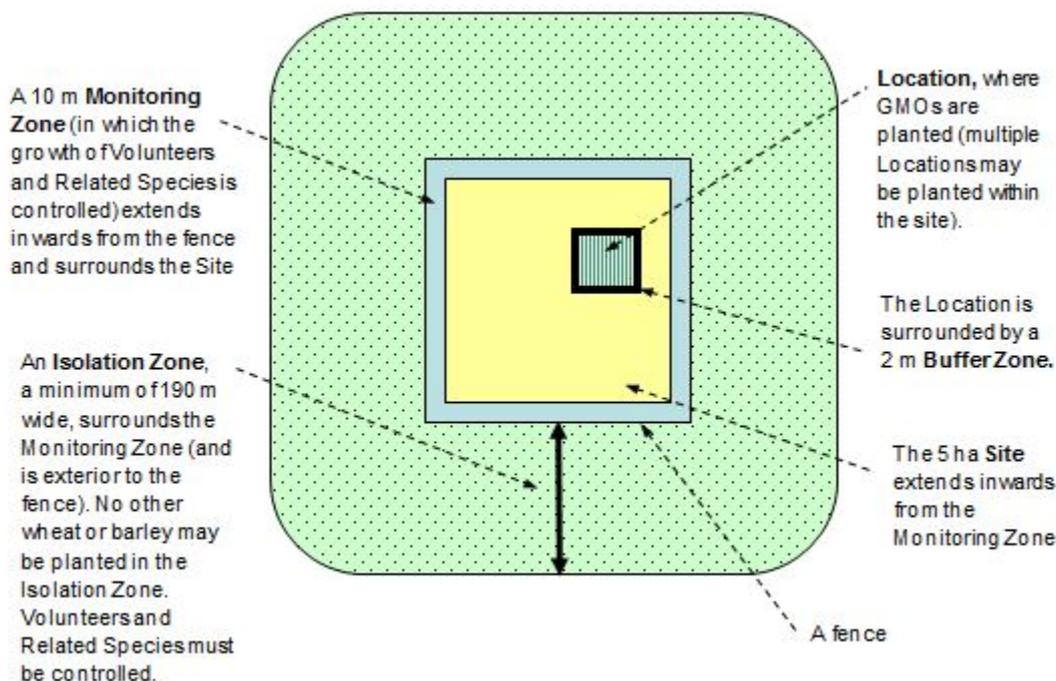
41. The Licence holder must not permit Related Species to be planted within the Isolation Zone while the GMOs are growing in the Location(s).

Note: Other conditions of this Licence require inspections for, and control of Related Species and Volunteers in the Location, Buffer Zone, Monitoring Zone, other areas with the Site and Isolation Zone while the GMOs are growing in the Location(s) (Section 8 – Inspections).

42. All areas within the Site, other than the Locations and Buffer Zones, or their equivalents under another licence, 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 Volunteers and Related Species growing amongst Break Crop Plants would be Destroyed prior to flowering.

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



Genetically modified organisms covered by other licences

43. Other genetically modified plants may be approved by the Regulator under a separate licence for release within the Site. These plants may be grown within the Site provided they are not grown in an area which is a Location or Buffer Zone of this licence.

Transport, Storage and Use

Note: This licence does not expressly authorise or prohibit any dealings or storage in certified physical containment 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.

44. Plant Material may only be transported to the extent necessary to store it, Destroy it, export it, Clean it from Equipment, or relocate it to a Location, to a facility approved for experimentation and/or storage under this licence, or to a PC2 facility.

45. Any Plant Material transported or stored outside the Site must be transported and stored in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as current at the time of transportation and storage. Routes, methods and procedures used for this transportation under this licence must be documented and provided to the Regulator on request.

46. Plant Material collected or harvested from a Location may be used for experimentation or analysis or storage provided the experimentation, analysis and storage takes place:

- (a) within a Location; or
- (b) in a facility approved in writing by the Regulator.

47. 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 feed for animals or food for humans.

48. If genetically modified organisms other than those authorised by this licence are:

(a) grown under 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 GMOs grown under this licence must not be used in the future development of cultivars for commercial release.

(Note: Under the situation described in condition 48, any conditions regarding the use of seed derived from GMOs approved under a separate licence would be provided in that licence.)

Harvest, Cleaning and Disposal

Harvest and threshing

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

50. If the GMOs or Plant Material from a Location are harvested, they must be harvested by hand, the use of a small mechanical single-row harvester, or a plot harvester.

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

51. Harvesting must be conducted in a manner so as to avoid dispersal of Plant Material outside the Location and Buffer Zone

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 on the Location or in a facility approved in writing by the Regulator.

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.

Cleaning of Equipment

53. Cleaning of Equipment used in connection with the GMOs in a Location must occur within the Site or in the Wash Down Facility, and as soon as practicable after use and before it is used for any other purpose. The Wash Down Facility itself must also be cleaned as soon as practicable after use and before it is used for any other purpose.

Note: As the Wash-Down facility is considered as an Equipment, it does not require a Sign-off, but after Cleaning may be used in connection of the GMOs. After each use with GMOs, Cleaning is required.

Cleaning of Places

54. The following areas must be Cleaned as soon as practicable after use:

(a) any areas used to Clean Equipment used in connection with the GMOs or Plant Material or to Destroy the GMOs or Plant Material; and

(b) any other areas where the GMOs or Plant Material have been dispersed during harvesting.

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

Note: If Tillage is adopted as a method of Destruction for the purpose of condition 55, it must comply with conditions 56 and 60 of this Licence.

Note: Other conditions of this Licence require the Licence Holder to make records and give notices to the Regulator in relation to Cleaning of Places and of the Wash Down Facility (Section 9 – Reporting and Documentation Requirements).

Conditions on use of Locations after harvest and Places after Cleaning

56. A 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.

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

58. 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 Place

Note: Break Crop plants must be managed according to condition 42.

59. Prior to an application for Sign-off, a Place 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. Evidence, such as rainfall equal to or above that normally applied during irrigation or photos that the rainfall has been sufficient to promote germination, should be provided.

60. Prior to the last irrigation referred to in the immediately preceding condition, the Place must be tilled to a depth no greater than the depth of sowing.

61. Additional tillage may be conducted but tillage must not be to a depth greater than the depth of sowing of the GMOs.

Sign-off

62. The licence holder may make written application to the Regulator for Sign-off of a Place if 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 at least one tillage and three irrigations or rainfall events for all Places prior to a Sign-off application (see Section 7 – 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 and irrigation regimes,

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.

Inspections

63. Inspections must be performed by a person who is able to recognise Volunteers and Related Species.

Inspections and associated actions must be undertaken according to Table 1.

Table 1. Inspection requirements

Area	Period of inspection	Inspection frequency	Inspect for	Action
During growth of GMOs				
Location and Buffer Zone	from 14 days prior to the expected commencement of Flowering until the Location has been Cleaned	At least once every 14 days	Volunteers & Related Species	Prevent from Flowering
Monitoring Zone			Volunteers & Related Species	
Fence surrounding the Site			Damage	Repair immediately to maintain exclusion of livestock
Isolation Zone			from 14 days prior to the expected commencement of flowering of any GMOs until all GMOs in the Site have finished flowering	Volunteers & Related Species
Site, <i>ie</i> all growing areas of the NGNE facility, other than within Locations or Places	from 14 days prior to the expected commencement of flowering until all Places in the Site have been Signed-off	At least once every 35 days	Volunteers & Related Species	Prevent from Flowering
Post-Cleaning				
Place	from the day of Cleaning and continuing until the Place is replanted with GMOs or the Regulator has issued a Sign-off	At least once every 35 days	Volunteers & Related Species	Prevent from flowering
Site, <i>ie</i> all growing areas of the NGNE facility, other than within Locations or Places	continuing from above inspection during growing of the GMOs until all Places in the Site have been Signed-off	At least once every 35 days	Volunteers & Related Species	Prevent from Flowering

Note: A range of information about inspection activities must be recorded and provided to the Regulator (see Section 9 – Reporting and Documentation Requirements).

Reporting and Documentation Requirements

Contingency Plan for unintended presence of Plant Material

64. 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.
65. 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; 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.
66. 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.

Extreme weather conditions

67. The licence holder must immediately, by notice in writing, inform the Regulator of any extreme weather conditions that have affected or are expected to affect the Site whilst the GMOs are growing or whilst subject to inspection requirements.

Notice of intention to plant and actual planting

68. At least 7 days prior to the date on which planting of the GMOs is intended to commence at any Location, the licence holder must provide a notice in writing to the Regulator which contains:
- (a) the date on which planting of the GMOs is intended to commence;
 - (b) the date on which planting of any non-GM Wheat or Barley in the Location is intended to commence;
 - (c) detail of the Location, including the GPS coordinates and dimensions (in metres);
 - (d) the identity of the GMOs which are intended to be planted;
 - (e) the period during which the licence holder considers the GMOs are likely to flower;
 - (f) the period during which the licence holder considers the GMOs are likely to be harvested;
 - (g) the period(s) during which the licence holder considers the Location and associated Buffer Zone are likely to be Cleaned;
 - (h) if GMOs have previously been planted at the 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; and
 - (i) a description of how the Location is intended to be used during the first 2 years following harvest of the GMOs.
69. Within 7 days of planting of the GMOs, the licence holder must provide a notice in writing to the Regulator indicating the actual date on which planting of the GMOs occurred and any changes in the details provided under the immediately preceding condition.

Notice of harvest and Cleaning

70. Within 7 days of commencement of harvesting of the GMOs at a Location, the licence holder must provide the actual date of commencement of harvesting of the GMOs at a Location.
71. 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.
72. On the request of the Regulator, the licence holder must provide written documentation of the procedures in place to ensure continuing compliance with the Cleaning conditions in this licence.

Notices of inspection activities

73. Information about 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 experience, training or qualification that enables each person to recognise Volunteers and Related Species, if not already recorded in the logbook;
 - (d) details of the areas inspected;
 - (e) 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;
 - (f) details of any rainfall events at the Location or Place, including measurements of any rainfall at or near the Location or Place;
 - (g) the means of inspection used;
 - (h) the number of Volunteers and Related Species observed, if any;
 - (i) details of where within the area inspected Volunteers, if any, are observed (*eg* by marking on a map);
 - (j) details of the developmental stages reached by the Volunteers or Related Species, if any;
 - (k) details of methods used to Destroy Volunteers or Related Species, if any, and the date of destruction, if different from the date of inspection;
 - (l) details of rodent control methods used, if any;
 - (m) details of any repairs required to the fence surrounding the Site.
74. The information about inspections as recorded in the Logbook must be forwarded to the Regulator within 35 days of inspection taking place.

Other records to be kept

75. The licence holder must keep records of any Cleaning of the Wash Down Facility, including the means of Destruction of any plant material, in a Logbook and provide the information in the Logbook to the Regulator upon request.

76. The licence holder must keep records of the 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.

Testing methodology

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 in a recipient organism. The detection method must be capable of reliably distinguishing between the categories of GMOs described in this licence. The instrument must be provided before planting of GMOs under this licence.

DIR No: 112

***Full Title:** Limited and controlled release of wheat and barley genetically modified for altered grain composition and nutrient utilisation efficiency

Organisation Details

Postal address: CSIRO Plant Industry
GPO Box 1600
Canberra ACT 2601

Phone No: (02) 6246 4943

Project Supervisor Details

Surname: *[Personal information redacted]*
First Name: *[Personal information redacted]*
Title: *[Personal information redacted]*
Phone No: *[Personal information redacted]*
Fax: *[Personal information redacted]*
Email Address: *[Personal information redacted]*
Position: *[Personal information redacted]*
Organisation: Commonwealth Scientific and Industrial Research Organisation
Postal Address: CSIRO Plant Industry
GPO Box 1600
Canberra ACT 2601

IBC Details

IBC Name: IBC 103 (CSIRO Plant Industry)

ATTACHMENT B

GMO Description

GMOs covered by this licence:

Triticum aestivum spp. and *Hordeum vulgare* L containing only the genes, marker genes and genetic elements listed below.

*Parent Organism:

Common Name: Wheat and Barley

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

*Modified traits:

Categories: Composition
Yield
Selectable marker - antibiotic

Description: Wheat and barley plants have been genetically modified for altered grain composition and nutrient utilisation efficiency. Most plants also contain antibiotic resistance markers.

*Genetic elements responsible for conferring the modified traits:

One partial gene from wheat (*T. aestivum*) for altered grain composition and one gene from barley (*H. vulgare*) for nutrient utilisation efficiency.

hpt gene from the bacterium *Escherichia coli*

nptII gene from the bacterium *E. coli*

Refer to Table 2 of this attachment for details. Note that plasmid vector sequences, including the ampicillin resistance gene under the control of bacterial expression sequences, may also be present in some GMOs.

Purpose of the dealings with the GMOs:

CSIRO applied for a licence for dealings involving the intentional release of up to 118 GM wheat and 40 GM barley lines on a limited scale and under controlled conditions. 23 wheat lines have been genetically modified for altered grain composition. 95 wheat lines and 40 barley lines have been genetically modified for nutrient utilisation efficiency.

The purpose of the trial is to:

- assess under field conditions whether the respective genetic modifications result in increased biomass and yield in the GM plants compared to controls
- produce sufficient grain to allow replicated field trials in years two and three to characterise biomass and yield characteristics
- analyse any changes in grain composition, dough making properties and end product quality.

The GM wheat and barley is not permitted to enter the human food or animal feed supply chains.

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

Table 2. The genes and constructs used to generate the GM wheat and barley lines authorised for release.

Gene of interest (Source organism ^b)	Anticipated effect of introduced gene	Construct	Parental cultivar	Max no of GM lines	Previous DIR licence	
Group 1 - Glucan water dikinase RNAi						
RNAi targeting <i>GWD</i> (<i>Ta</i>)	Suppression of <i>GWD</i> gene in the endosperm leading to altered grain composition	pBX17GWDcasNOT	Bobwhite 26	3	092, 099	
		pBX17GWDtwin	Bobwhite 26	10	New	
		pBX17GWDdrb	Bobwhite 26	10		
Group 2 - Alanine aminotransferase						
<i>AlaAT</i> (<i>Hv</i>)	Increase plant biomass and yield through improved nitrogen use efficiency	pARC425	Bobwhite 26	3	094, 099	
		pMDC/POsAnt1	Bobwhite 26	15	094, 099	
		HvAlat Nos	Frame		2	094, 099
			Gladius		15	New
			Golden Promise		20	094, 099
		pARC316	Gladius	20	New	
		pARC316drb	Bobwhite 26	20		
pARC425drb	Bobwhite 26	20				
pMDC-MF1/POsAnt1	Golden Promise	20				
	HvAlat Nos					

^a *Hv*=*Hordeum vulgare*; *Ta*=*Triticum aestivum*.