



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 099

Licence holder: The Commonwealth Scientific and Industrial Research Organisation

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

Issued: 11 June 2010
Varied 21 February 2011

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

Gene Technology Regulation in Australia

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

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

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

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

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

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

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

Information about where the GMOs have been planted pursuant to this licence can be found in a separate document entitled 'DIR 099 Site Details'. This document can be accessed on the OGTR website at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir099>.

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 of the species canola, lupins, field peas, cotton, millet or sorghum, or 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:

- (a) uprooting;
- (b) ploughing;
- (c) burning/incineration;
- (d) treatment with herbicide;
- (e) autoclaving,
- (f) crushing, 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 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), 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 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 from the outer edge of the Monitoring Zone (see figure 1).

'Location' means an area of land where the GMOs 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 metres from the outer edge of a Site (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 be required to be, or which has been, Cleaned pursuant to this licence (see figure 1).

'Plant Material' means any part of the GM or non-GM Wheat and Barley plants grown at a Location 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 two or more plants per 10 square metres of land.

'Related Species' means plants of the species *Hordeum vulgare* L. and plants in the genera *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 obligations no longer apply in respect of that Site.

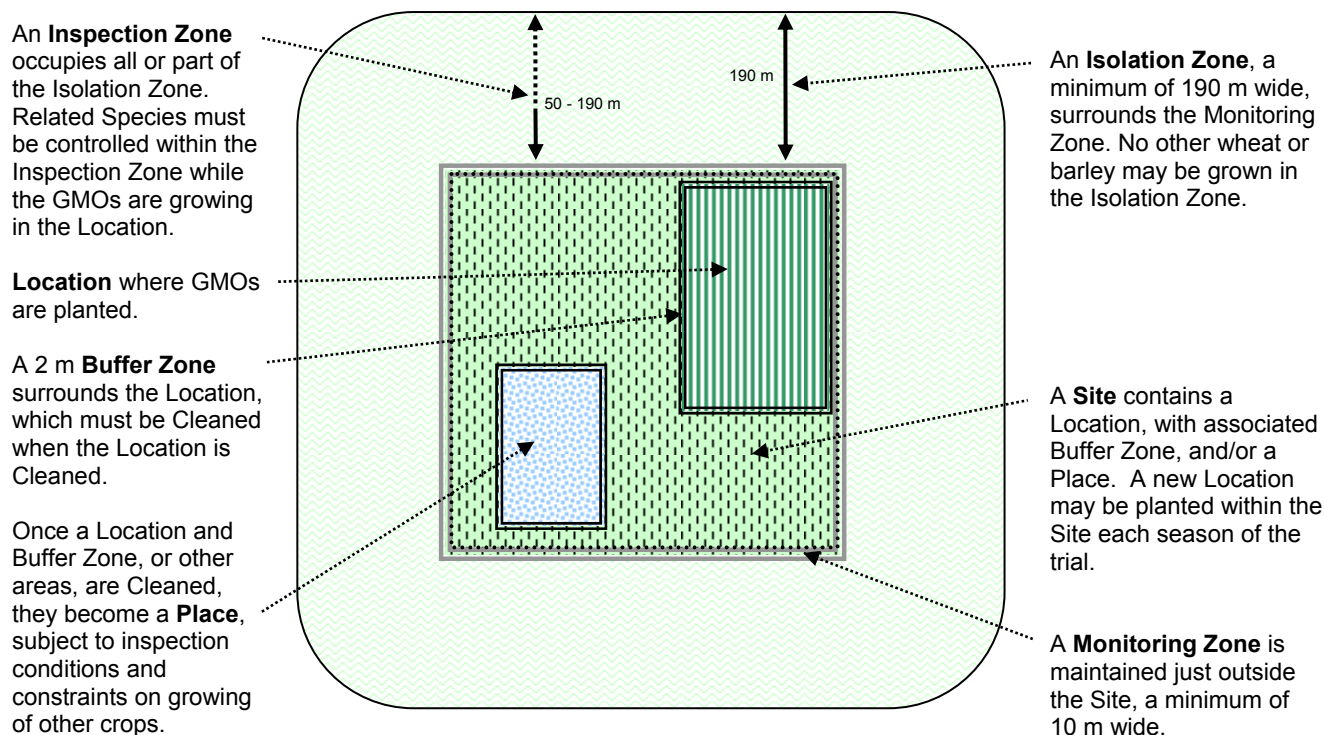
'Site' means an area of land within which a Location and associated Buffer Zone may be established (see figure 1).

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

'Wash Down Facility' means an area, 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.

Figure 1. Diagram showing the relationship between a Location, a Place, a Site, 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 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 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, Monitoring and Isolation Zones, 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 Licence holder must notify the Regulator 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 a Location must be handled and controlled as if they were 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 June 2013, inclusive, within a single Site in each of the local government areas of Narrabri in New South Wales and Merredin in West 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 1 hectare per Location.

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.

34. A Location and associated Buffer Zone must be within a Site.

35. The Site in the local government area of Merredin must be within a fenced area capable of excluding livestock, with lockable gates which must be locked except when accessed by persons covered by the licence.

36. The site at Merredin may have a Wash Down Facility provided that it is immediately adjacent to the fenced area.

37. The Site in the local government area of Narrabri must be within a farm which is surrounded by a fence capable of excluding livestock.

38. Measures must be implemented to control rodent numbers in each Location. These may include, but are not limited to, traps and/or poison bait within and/or surrounding the Location while GMOs are being grown and until the Site has been Cleaned.

39. Each Site must be surrounded by a Monitoring Zone, and the Monitoring Zone must be surrounded by an Inspection Zone and an Isolation Zone.

40. 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.

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

42. 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 65 and 67 in the previous growing season; and

(iii) it is agreed to in writing by the Regulator.

43. 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 within the Site and Inspection Zone while the GMOs are growing in the Location (Section 7 – Inspections).

44. 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

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.

Plant Material not to be used in food or animal feed

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

Experimentation and storage

46. 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.

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

48. 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

49. 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.

50. 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

51. 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.

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

53. 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 secateurs.

54. 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.

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.

55. 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 or at the adjacent Wash Down Facility, so as to prevent dispersal of viable Plant Material.

56. 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.

57. 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.

58. Each 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 Places (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

59. A Location or 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.

60. 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 Site.

61. 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 relevant Site.

Note: Break Crop plants are subject to management requirements according to condition 44.

62. 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.

63. All Places in the Site must be tilled to a depth no greater than the depth of sowing prior to the last irrigation referred to in the immediately preceding condition.

Section 7 Inspections

64. Inspections must be performed by a person who is able to recognise Volunteers 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

65. Inspections of the Inspection 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 GMOs in the Location have finished flowering.
66. Inspections of the Site, including the Location and Buffer Zone, the fence surrounding the Site (if any) 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.
67. The Inspection Zone must be inspected for Related Species, and any Populations of Related Species must be either Destroyed prior to flowering or prevented from flowering.
68. The Site and the Monitoring Zone 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.
69. For the Merredin Location, the surrounding fence must be inspected and any damage repaired immediately.

Post-Cleaning Inspections

70. 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 relevant Site.
71. Any Volunteers or Related Species in a Place subject to post-cleaning inspections must be Destroyed prior to Flowering.

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

Sign-off

72. 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 / 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 Plan for unintended presence of Plant Material

73. 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.

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

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

75. 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

76. At least 7 days prior to the date on which planting of the GMOs is intended to commence within a Location, 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 Barley in the Location is intended to commence;
- (c) details of the Site, 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 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
- (j) a description of how the Location is intended to be used during the first 2 years following harvest of the GMOs.

77. 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(s) on which planting of the GMOs occurred and any changes in the details required to be provided under the preceding condition.

78. 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.

79. 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

80. The licence holder must provide the Regulator with a notice of intention to harvest the GMOs at each Location. This notice must be provided at least 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.

81. 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.

82. 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.

83. 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

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

- (a) the date(s) 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 number of Volunteers or Related Species observed, if any;

- (g) details of the development stages reached by the Volunteers or Related Species, if any;
- (h) 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;
- (i) details of rodent control methods used, if any;
- (j) details of any repairs required to the fence surrounding the Merredin Location.

85. 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.

86. The licence holder must keep records of any cleaning of the Wash Down Facility in a logbook and provide the information in the record to the Regulator upon request.

Other records to be kept

87. The licence holder must keep records of the type 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

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

Note: Conditions 20 and 85 specify information to be included in an Annual Report.

Testing methodology

89. 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 different categories of GMOs described in this licence. The instrument must be provided within 30 days of the issuing of this licence.

DIR No: 099

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

Organisation Details

Postal address: *CSIRO Plant Industry
GPO Box 1600
CANBERRA ACT 2601

Phone No: 1300 363 400

Project Supervisor Details

Surname: *[Personal Information Redacted]*
First Name: *[Personal Information Redacted]*
Title: *[Personal Information Redacted]*
Phone No: *[Personal Information Redacted]*
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Organisation: Commonwealth Scientific and Industrial Research Organisation (CSIRO)

Postal Address: * CSIRO Plant Industry
GPO Box 1600
CANBERRA ACT 2601

IBC Details

IBC Name: IBC 103 (CSIRO Plant Industry)

GMO Description**GMOs covered by this licence:**

Triticum aestivum spp. and *Hordeum vulgare* L containing only the genes, the marker genes and the 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: Altered grain composition
Nutrient utilisation efficiency
Antibiotic resistance

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

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

An RNAi construct that suppresses the expression of a starch metabolic enzyme gene

A metabolic enzyme gene expected to enhance the efficiency of nitrogen utilisation

nptII gene from *Escherichia coli*

hpt gene from *E. coli*

bla gene from *E. coli*

Purpose of the dealings with the GMOs:

CSIRO applied for a licence for dealings involving the intentional release of up to 11 lines of GM wheat and 3 lines of GM barley on a limited scale and under controlled conditions. Four of the GM wheat lines have been genetically modified for altered grain composition. The remaining GM wheat lines and the 3 GM barley lines have been genetically modified for enhanced nutrient utilisation efficiency.

The purpose of the trial is to assess the growth and yield characteristics of the GM plants when grown under field conditions. CSIRO also intends to generate sufficient grain to assess any changes in grain composition for the GM plants relative to non-GM plants and how this may affect dough characteristics and end-product quality.

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