



**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 092**

**Licence holder: The Commonwealth Scientific and Industrial Research Organisation**

**Title: Limited and controlled release of wheat genetically modified for altered grain composition**

Issued: 28 May 2009

Varied: 31 July 2009

**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 092 Site Details'. This document can be viewed by accessing the document on the OGTR website at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir092>.

## **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.

In this licence:

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

**'Annual Report'** means a written report provided to the Regulator within ninety (90) days of each anniversary of issue of this licence containing all the information required by this licence to be provided in the Annual Report.

**'Break Crop'** means plants of the species *Medicago sativa* or *Brassica campestris*.

**'Buffer Zone'** means, in respect of a Location, an area surrounding the GMOs extending outwards at least two (2) metres in all directions, and at least four (4) metres where the Location is adjacent to the border of the Fenced Area.

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

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

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

- (a) stalk pulling;
- (b) uprooting;
- (c) ploughing;
- (d) burning/incineration;
- (e) treatment with herbicide;
- (f) hand weeding;
- (g) autoclaving.

*Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, in the case of plants with mature seed heads still attached ploughing would not be appropriate due to the introduction of large numbers viable seeds into the seedbank.*

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

**'Fenced Area'** means an area of up to one point four four (1.44) hectares surrounded by a fence, containing the Location(s) and the associated Buffer Zone(s).

**'GM'** means genetically modified.

**'GMOs'** means the genetically modified organisms the subject of the dealings authorised by this licence, but does not include GMOs grown in the Fenced Area in accordance with condition 33 of this licence.

*Note: GM plants referred to in condition 33 will be subject to the conditions of the substantive licence which authorises dealings with those GMOs.*

**'GM product'** means a thing (other than a GMO) derived or produced from a GMO.

**'Harvest'** (or **'Harvested'**) means the removal of the GMOs or GM Plant Material at the Location prior to Cleaning of the Location.

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

**'Location'** means an area of land within the Fenced Area where the GMOs may be intentionally planted and grown pursuant to this licence, but does not include the Buffer Zone.

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

**'Natural Waterways'** means waterways other than irrigation channels, holding dams or storage ponds used to collect water runoff from irrigated areas.

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

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

**'Place'** means an area required to be cleaned and/or inspected under this licence.

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

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

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

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

**'Triticaceae Population'** means two (2) or more plants per ten (10) square metres of land belonging to the genera *Triticum*, *Aegilops* or *Secale*.

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

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

## **Section 2 General conditions**

### **Duration of Licence**

3. 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**

4. The holder of this licence ('the licence holder') is the Commonwealth Scientific and Industrial Research Organisation.

### **Project Supervisor**

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

6. 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**

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

### ***Persons covered by this GMO licence***

8. 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.

9. 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.*

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

### ***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, and
  - iii) has not conducted the dealing without being informed of the condition, or its variation.

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

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

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

16. The licence holder must notify the project supervisor and all persons covered by a licence that Personal Information collected by the licence holder which is relevant to the administration and/or enforcement of the licence may be released to the Regulator.

***Applicant to notify of circumstances that might affect suitability***

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;
- (b) any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment;
- (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it.

***Licence holder must provide information on matters related to suitability***

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.

***Additional information to be given to the Regulator***

19. It is a condition of this licence that the licence holder informs the Regulator if the licence holder:

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

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

- (a) *the licence holder will be taken to have become aware of additional information if he or she was reckless as to whether such information existed; and*

*(b) the licence holder will be taken to have become aware of contraventions, or unintended effects, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

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.

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

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.

22. If a person is required by this licence to comply with a particular condition relating to a GM product, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises for the purposes of auditing or monitoring compliance with the condition.

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

24. 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, agreements, 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.

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

### ***Remaining an Accredited organisation***

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

### ***Notices***

27. The licence holder must provide all notices to the Regulator required to be given by this licence and each notice must be provided in the manner required by Section 7 of this licence.

## ***Section 3 Growing the GMOs***

### ***GMOs covered by this licence***

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

### ***Permitted dealings***

29. The permitted dealings with the GMOs are to plant, grow, propagate, harvest, transport and dispose of the GMOs, to conduct experiments with 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 for the purpose of any of the permitted dealings with the GMOs, or in the course of any of these dealings.

30. The GMOs may be planted only at one (1) Location in 2009 and 2010, and, subject to condition 31, at up to two (2) Locations in 2011, if one (1) of the Locations is the Location from 2009.

31. A Location may be replanted with the GMOs in subsequent years and prior to Site Sign-off if a period of more than sixteen (16) months occurs between the Harvest of the first planting and subsequent replanting at that Location. If replanting occurs, the GMOs replanted at a Location are subject to these licence conditions as if it were the first planting.

### ***Non-GM Plants***

32. Plant Material from non-GM plants grown within the Fenced Area must be handled and controlled as if it were Plant Material from the GMOs (ie subject to other conditions elsewhere in this licence).

### ***GMOs covered by other licences***

33. GM plants approved for release by the Regulator under a separate licence may be grown within the Fenced Area provided:

- (a) they are grown at a Location approved under the separate licence; and
- (b) they are separated by at least four (4) metres of Buffer Zone from the GMOs covered by this licence as described in Attachment B.

### ***Limits - Locations, timing and size of trial***

34. With respect to the permitted dealings described in condition 29, planting, growing, propagating and harvesting must only be undertaken between July 2009 and June 2012, inclusive, within the Australian Capital Territory at Ginninderra Experimental Station.

35. Intentional planting of the GMOs must occur within the Fenced Area, and the maximum combined area of all Locations and associated Buffer Zones must not exceed one (1) hectare.

### ***Notice of intention to plant, of planting and of flowering***

36. The licence holder must, in the manner required by condition 90, give advance notice to the Regulator of an intention to plant the GMOs.

37. The licence holder must, in the manner required by condition 91, give notice to the Regulator of the actual date of planting the GMOs.

38. The licence holder must, in the manner required by condition 93, give notice to the Regulator of the actual date of commencement of each flowering season of the GMOs.

### **Containment measures**

39. A Location must be surrounded by a Buffer Zone which must consist of:
- (a) non-GM Wheat provided it is not allowed to produce viable seed; or
  - (b) any species that is not a Related Species; or
  - (c) an area free of any vegetation and/or vegetation kept mown to a height of less than ten (10) centimetres

provided that the Buffer Zone does not restrict the ability for recognition and destruction of Related Species as required by conditions 69-71.

40. The outer edge of the Fenced Area must not be within fifty (50) metres of a Natural Waterway.

41. The Fenced Area must be surrounded by a fence at least 1.8 metres high capable of excluding large animals, with lockable gates which must be locked except when accessed by persons covered by this licence. The fence must be inspected regularly and any damage allowing access by large animals, such as livestock, repaired immediately and reported to the Regulator within fourteen (14) days.

42. The Fenced Area must be surrounded by a Monitoring Zone and an Isolation Zone.

43. 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 first tillage after harvest. Measures to achieve this could include land free of any vegetation and/or vegetation kept mown to a height of less than ten (10) centimetres.

44. Appropriate measures must be implemented to control rodent numbers in the Fenced Area. These may include, but are not limited to, traps and/or poison bait within and/or surrounding the Fenced Area while GMOs are being grown and until the Site has been Cleaned.

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

## **Section 4 Use of Plant Material**

### **Experiment and storage**

46. Experiments and/or analysis of Plant Material are only permitted if:
- (a) the experiments and/or analysis are a notifiable low risk dealing; and
  - (b) the experiments and/or analysis do not involve the feeding of the Plant Material to humans or animals, except as allowed under condition 50.

*Note: A dealing will only be a notifiable low risk dealing if:*

- (a) an Institutional Biosafety Committee has been asked to assess whether the proposed dealing is a notifiable low risk dealing; and*
- (b) the Committee has assessed the proposed dealing to be a notifiable low risk dealing; and*

- (c) *the person who proposes to undertake the proposed dealing and the project supervisor for the proposed dealing have been notified that the Committee;*
- i) *has assessed the proposed dealing to be a notifiable low risk dealing; and*
- ii) *considers that the personnel to be involved in the proposed dealing have appropriate training and experience.*

47. Any Plant Material that is collected for experiments and/or analysis may be transported off Site to:

- (a) a facility certified by the Regulator to physical containment level 2 (PC2); or
- (b) a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is stored within the facility

and may be experimented on and/or analysed and must be Destroyed as soon as practicable.

48. If the GM Wheat grain is milled, milling must take place in a PC2 certified laboratory.

#### ***Plant Material not to be used in food***

49. Subject to condition 50 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.

50. Non-viable products derived from the GMOs specified for animal nutritional experiments in Attachment B may be fed to rats and pigs for the purpose of nutritional experiments, subject to those experiments being approved by an Animal Ethics Committee operating under The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes.

51. With respect to the preceding condition, rat nutritional experiments may only be conducted at the CSIRO Human Nutrition Small Animal Facility in Adelaide, SA, and pig nutritional experiments may only be conducted at either the Victorian Institute of Animal Science (Werribee, Victoria) or at the CSIRO Livestock Industries Werribee Animal Facility (Werribee, Victoria).

52. If products derived from the GMOs are fed to rats or pigs outside a PC2 facility, residual feed and material collected from the animals (including faeces) must be buried or burnt.

### ***Section 5 Transport, Cleaning and Disposal***

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

#### ***Notice of Harvest and cleaning following Harvest***

54. The licence holder must, in the manner required by condition 94, provide the Regulator with a notice of intention to Harvest the GMOs at the Location.

55. The licence holder must, in the manner required by condition 95, provide the actual date or dates of the commencement of Harvesting of the GMOs at the Location.

56. The licence holder must, in the manner required by condition 96, give notice to the Regulator of the date on which Cleaning of the Place concluded.

### ***Harvest and post-Harvest procedures***

57. If the GMOs or Plant Material from a Location are Harvested, they must be harvested by hand, or through the use a single-row 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.*

58. If a single-row harvester is used to Harvest the GMOs, appropriate measures must be in place to ensure that GM Wheat seed or other Plant Material is not dispersed during Harvesting, and the resulting waste Plant Material collected and Destroyed.

59. If the GMOs or Plant Material from a Location are Harvested, they must be Harvested separately from any other crop, including material from any GM plants approved under a separate licence.

60. If seed Harvested from the GMOs or Plant Material is threshed, it must be threshed separately from any other crop, including material from any GM plants approved under a separate licence.

61. If a thresher is used, appropriate measures must be in place to ensure that GM seed or other Plant Material is not dispersed during threshing. Threshing must be done within the Fenced Area or in a PC2 facility.

### ***Transportation of Plant Material***

62. Plant Material may only be transported to the extent necessary to store it, Destroy it, export it, Clean it from Equipment, relocate it to a facility approved by the Regulator or to a PC2 facility, or relocate it to the Site from a facility approved by the Regulator or from a PC2 facility.

63. Any Plant Material transported must be transported in accordance with the guidelines for the transportation of GM Plant Material found in the Regulator's *Guidelines for the Transport of GMOs* as current at the time of transportation, and routes, methods and procedures used for this transportation in accordance with this licence must be documented and provided to the Regulator on request.

### ***Cleaning of Equipment and Places***

64. Cleaning of Equipment must occur within the Fenced Area immediately or as soon as practicable after use and before it is used for any other purpose. Equipment used for sowing, Harvesting and threshing must be Cleaned between use for any GM plants approved under a separate licence.

65. The following Places must be Cleaned:

- (a) the Locations and the Buffer Zones;
- (b) any areas used during Harvest or threshing;

- (c) any areas used to Clean Equipment used in connection with the GMOs or Plant Material or to Destroy the GMOs or Plant Material.

66. The Location and Buffer Zone must be Cleaned before the end of the first May following each Harvest. All other Places in respect to each Location must be cleaned within fifteen (15) days of Harvest or Destruction of the GMOs.

## ***Section 6 Use of Site and Site sign off***

67. Inspections must be performed by a person who is able to recognise Volunteer Plants, Related Species and Triticaceae Populations.

68. The licence holder must, in the manner required by condition 98, record the results of all inspection activities and forward the results to the Regulator.

### ***Inspections to be conducted in the Fenced Area, including the Location and Buffer Zone, while the GMOs are being grown***

69. Fourteen (14) days before the expected commencement of flowering of the GMOs at a Location, as notified to the Regulator pursuant to this licence, the Fenced Area must be inspected for the presence of Related Species that are not the GMOs or plants from other intentional releases approved by the Regulator to be grown within the Fenced Area.

70. If any Related Species that are not the GMOs and not plants from other intentional releases approved by the Regulator to be grown within the Fenced Area are found they must be Destroyed before flowering.

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

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

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

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

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

74. Fourteen (14) days before the expected commencement of flowering of the GMOs at a Location, as notified to the Regulator pursuant to this licence, the Isolation Zone must be inspected for the presence of Triticaceae Populations, and any Triticaceae Population found must be Destroyed prior to flowering.

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

### ***General conditions on use of Location post-Harvest***

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

- (a) the Regulator has issued a Sign-off for the Site; or
- (b) the plants are plants agreed to in writing by the Regulator; or
- (c) the plants are plants allowed under condition 31; or
- (d) the plant is a Break Crop and the planted area is treated with selective herbicides such that any Volunteer Plants growing amongst the Break Crop would be Destroyed prior to flowering.

77. Unless permitted in accordance with the previous condition, no plants may be grown in the Fenced Area unless the plants are a Break Crop or plants agreed to in writing by the Regulator. Any Break Crops planted in the Fenced Area must be treated with selective herbicides such that any Related Species growing amongst the Break Crop would be Destroyed prior to flowering.

78. Locations and associated Buffer Zones must be irrigated at least three (3) times, at intervals of at least twenty eight (28) days, with the first irrigation occurring within sixty (60) days of each Harvest, so as to promote the growth of Volunteer Plants.

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

79. Locations and associated Buffer Zones must not be tilled between Harvest and the first irrigation following Harvest, so as to promote after-ripening of grain remaining on the soil surface. Sites must be tilled prior to the third irrigation following Harvest, to a depth no greater than the depth of sowing.

80. Wheat stubble may be retained on the Location following Harvest until the tillage required in the immediately preceding condition, before being Destroyed.

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

### **Post-Harvest (or post-Destruction) Inspections**

81. Following Harvest, all Places Cleaned must be inspected for the existence of Volunteer Plants and Related Species.

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

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

84. For each Location, all Places required to be inspected must be inspected at least once every thirty five (35) days commencing on the last day of Harvest of the GMOs and continuing until the Regulator has issued a Sign-off for the relevant Site; or, subject to conditions 30 and 31, the Location is replanted.

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

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

### **Sign-off**

86. For each Site,

- (a) if inspections have been routinely completed for a period of at least twenty four (24) months, and
- (b) if inspection records for that Site show that no Volunteers have been observed in the most recent six (6) month inspection period, provided that each Location and associated Buffer Zone has been irrigated at least once in the most recent six (6) month inspection period such that it would allow the germination of Volunteer Plants,

the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site.

## **Section 7 Reporting and Documentation Requirements**

### **Contingency Plans**

87. Within thirty (30) days of the date of issue of this licence, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event of the unintended presence of the GMOs or Plant Material outside an area that must be inspected.

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

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

89. 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**

90. At least seven (7) days prior to the date on which planting of the GMOs is intended to commence, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the date on which planting of the GMOs is intended to commence;
- (b) the date on which planting of any non-GM Wheat on a Location is intended to commence;
- (c) details of the Fenced Area and Location where the GMOs will be planted, including the size of the Fenced Area, a street address and GPS coordinates for the Fenced Area; and the GPS coordinates for the Location, the dimensions (in

metres) of the Location, details of the Location relative to the Fenced Area and details of the Location relative to any other Location in the Fenced Area;

- (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 GMOs are likely to be Destroyed;
- (h) if GMOs have previously been planted at a Location, a history indicating how the Location has been used in the preceding two (2) years, including details of previous GMOs and post-Harvest crops planted at the Location; and
- (i) a description of how the Location is intended to be used during the first two (2) years following Harvest of the GMOs.

91. Within seven (7) days of planting of the GMOs, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the actual date on which planting of the GMOs occurred;
- (b) the actual date on which planting of any non-GM Wheat on a Location occurred;
- (c) details of the Fenced Area and Location where the GMOs were planted, including the size of the Fenced Area, a street address and GPS coordinates for the Fenced Area; and the GPS coordinates for the Location, the dimensions (in metres) of the Location, details of the Location relative to the Fenced Area and details of the Location relative to any other Location in the Fenced Area;
- (d) the identity of the GMOs which were planted;
- (e) the period during which the licence holder considers the GMOs are likely to flower;
- (f) the period during which the licence holder considers the GMOs are likely to be Harvested;
- (g) the period(s) during which the licence holder considers the GMOs are likely to be Destroyed;
- (h) a description of how the Location is intended to be used during the first two (2) years following Harvest of the GMOs.

92. Fourteen (14) days before the expected commencement of each flowering season of the GMOs, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the date on which flowering of the GMOs is expected to commence;
- (b) the period during which the licence holder considers the GMOs likely to remaining flowering;

- (c) the period during which the licence holder considers the GMOs are likely to be Harvested;
- (d) the period(s) during which the licence holder considers the GMOs are likely to be Destroyed.

93. Within seven (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:

- (a) the actual date on which flowering of the GMOs commenced;
- (b) the period during which the licence holder considers the GMOs likely to remaining flowering;
- (c) the period during which the licence holder considers the GMOs are likely to be Harvested;
- (d) the period(s) during which the licence holder considers the GMOs are likely to be Destroyed.

#### ***Notice of Harvest and Cleaning following Harvest***

94. The licence holder must provide the Regulator with a notice of intention to Harvest the GMOs at the Location. This notice must be provided at least seven (7) days, and not more than twenty one (21) days, in advance of the intended date of Harvest set out in the notice. Any change of intention prior to the intended Harvest date must be notified to the Regulator as soon as is reasonably and practically possible.

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

96. The licence holder must provide a notice in writing to the Regulator when a Place is Cleaned following Harvest. The notice must be provided to the Regulator within fourteen (14) days of the date on which Cleaning of the Place concluded.

97. On the request of the Regulator, the Regulator must be provided with written documentation of the procedures in place to ensure continuing compliance with the Cleaning conditions in this licence.

#### ***Results of inspection activities***

98. The results of all inspection activities must be recorded in a logbook or paper file. The findings of the inspections as recorded in the logbook or paper file must be forwarded to the Regulator within fourteen (14) days of inspection taking place and must also be included in the licence holder's Annual Report to the Regulator. The logbook or paper file must contain at least the following:

- (a) details of the areas inspected;
- (b) details of current land use (eg type of crop being grown) and of recent land management practices (eg irrigation, cultivation or spraying) applied in the areas inspected;

- (c) details of any rainfall events at the Location including measurements of any rainfall;
- (d) details of the date of inspection;
- (e) the names of the person or persons who undertook the monitoring and details of the experience, training or qualification that enabled them to recognise Volunteer Plants and Related Species and Triticaceae Populations;
- (f) the means of inspection used;
- (g) the number of Volunteer Plants or Related Species or Triticaceae Populations observed, if any;
- (h) details of the development stages reached by the Volunteer Plants or Related Species or Triticaceae Populations, if any;
- (i) details of methods used to Destroy Volunteer Plants or Related Species or Triticaceae Populations, if any, and the date of destruction, if different from the date of inspection;
- (j) details of rodent control methods used, if any;
- (k) details of any repairs to fences required under condition 41.

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

### ***Annual Report***

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

### ***Testing methodology***

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

**DIR No: 092**

**\*Full Title:** Limited and controlled release of wheat genetically modified for altered grain composition

**Organisation Details**

**Postal address:** \*CSIRO Plant Industry  
GPO Box 1600  
Canberra City, ACT, 2601  
AUSTRALIA

**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*]

**Fax:** [*Personal Information Redacted*]

**Email Address:** [*Personal Information Redacted*]

**Position:** [*Personal Information Redacted*]

**Organisation:** Commonwealth Scientific and Industrial Research Organisation (CSIRO)

**Postal Address:** \*CSIRO Plant Industry  
GPO Box 1600  
Canberra City, ACT, 2601  
AUSTRALIA

**IBC Details**

**IBC Name:** IBC 103 (CSIRO Plant Industry)

## GMO Description

### **\*Parent Organism:**

Common Name: Wheat

Scientific Names: *Triticum aestivum* L. em Thell.

### **\*Modified traits:**

Categories: Altered grain starch composition  
Altered grain storage protein composition  
Antibiotic resistance

Description: Wheat plants have been genetically modified for altered grain composition. The plants may also contain an antibiotic resistance marker.

### **\*Genes responsible for conferring the modified traits:**

Refer to Table 1 of this attachment.

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

The Commonwealth Scientific and Industrial Research Organisation applied for a licence to release 16 lines of genetically modified (GM) wheat into the environment on a limited scale and under controlled conditions. The purpose of the trial is to generate enough grain to examine dough properties and end quality of grain products, and to conduct experiments to determine if nutritional value is altered. Some seed will be collected and retained for analysis and possible future trials, subject to further approval(s).

Grain storage proteins are important for determining dough characteristics such as extensibility and elasticity. Alteration of these characteristics may lead to improved or new wheat products. Alteration of grain starch characteristics may change the nutritional value of wheat products leading to health benefits.

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

**Table 1: Genes responsible for conferring the modified traits.**

Category	Maximum number of lines	GMO group	Constructs present <sup>1</sup>	Gene fragment in RNAi construct <sup>2</sup>	Construct description	Source of RNAi insert	Marker gene/s <sup>3</sup>	May be fed to animals <sup>4</sup>
Altered grain storage proteins	4	<i>γ-gliadin</i> RNAi	pBX17Gldup	One fragment from each of four <i>γ-gliadins</i>	<i>γ-gliadin</i> RNAi expression vector	Wheat	<i>NPTII</i> , <i>bla</i>	No
	2	<i>α-gliadin</i> RNAi	pBx17Adup	Two fragments from each of three <i>α-gliadins</i>	<i>α-gliadin</i> RNAi expression vector	Wheat	<i>NPTII</i> , <i>bla</i>	No
Altered grain starch	4	[this is Confidential Commercial Information]			RNAi expression vector	Wheat	<i>NPTII</i> , <i>bla</i>	Yes
	4	[this is Confidential Commercial Information]			RNAi expression vector	Wheat	<i>NPTII</i> , <i>bla</i>	Yes
	2	[this is Confidential Commercial Information]			RNAi binary vector	Wheat	<i>NPTII</i> , <i>bla</i>	Yes
					RNAi expression vector	Wheat		

<sup>1</sup> Constructs must be as described in table 2 of the Risk Assessment and Risk Management Plan (RARMP); all lines may also contain the construct pCMneoSTLS2, which contains the *NPTII* gene.

<sup>2</sup> Gene fragments must be as described in table 1 of the RARMP.

<sup>3</sup> Neomycin phosphotranferase II (*NPTII*) confers resistance to the antibiotic kanamycin and is expressed from the Cauliflower mosaic virus 35S promoter; b-lactamase (*bla*) is expressed from its own promoter; both genes are derived from *Escherichia coli*.

<sup>4</sup> Permission to feed GM Products to animals is subject to further licence conditions.