



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

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

**Licence No.: DIR 151**

**Licence holder: CSIRO**

**Title: Limited and controlled release of wheat genetically modified for disease resistance, drought tolerance, altered oil content and altered grain composition**

Issued: 01 May 2017

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 activities involving genetically modified organisms (GMOs).

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

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

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

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

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

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

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

## Section 1 Interpretations and definitions

1. In this licence:

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

2. In this licence:

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

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

- (a) in relation to a Planting Area, the Destruction of the GMOs in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and/or Destruction of the GMOs, to the reasonable satisfaction of the Regulator.

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

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

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

- (a) uprooting;
- (b) Tilling, but only subject to the conditions of this licence;
- (c) treatment with herbicide;
- (d) burning/incineration;
- (e) autoclaving;
- (f) milling;
- (g) crushing;
- (h) burial, but only subject to the conditions of this licence; or
- (i) a method approved in writing by the Regulator.

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

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

**'Facility'** means lockable facility to store seeds at the trial sites, or other facility approved in writing by the Regulator.

**'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. GMOs include live plants and viable seed. All Wheat plants grown at the Planting Area are considered GMOs for the purposes of this licence.

**'Isolation Zone'** means an area of land extending 190 metres in all directions from the outer edge of the Monitoring Zone where no Wheat or Related Species may be deliberately grown.

**'Logbook'** means a written or electronic record containing information required to be collected and maintained by this licence and which is able to be presented to the Regulator on request.

**'Monitoring Zone'** means an area of land extending outwards at least 10 m from the outer edge of the Planting Area, as indicated in Figure 1.

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

**'Personal Information'** means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

- (a) whether the information is true or not; and
- (b) whether the information is recorded in a material form or not.

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

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

**'Related Species'** means plants from the genus *Triticum*, except the GMOs and non-GM Wheat plants planted and grown according to this licence.

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

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

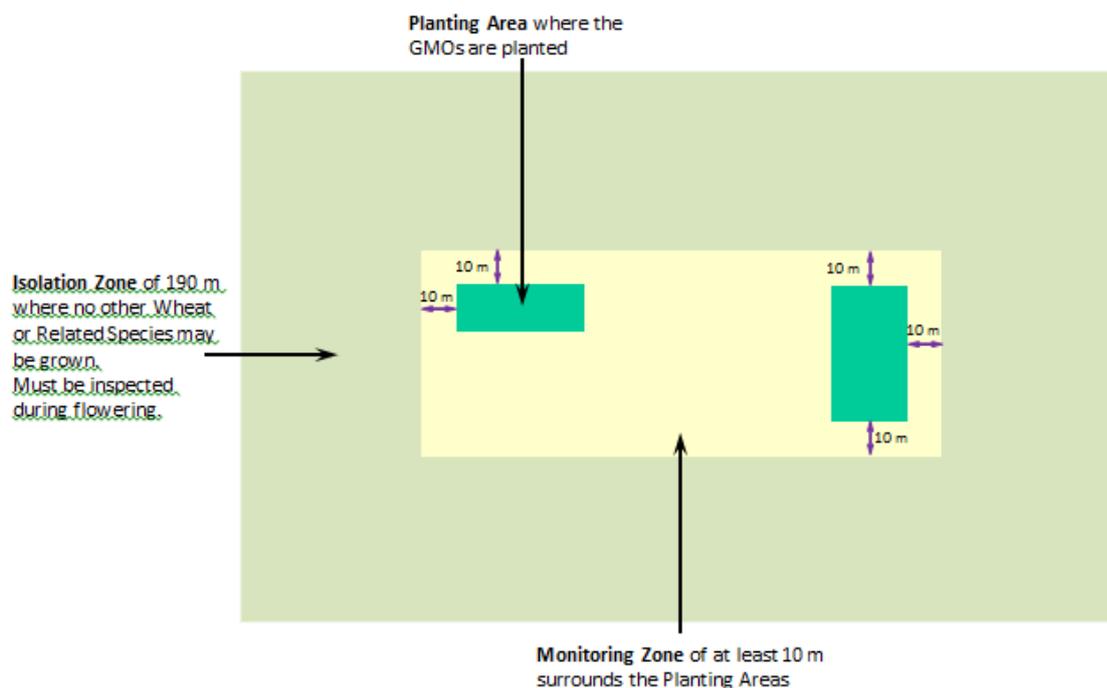
**'Site'** means the area of land within which one or more Planting Areas and associated Monitoring Zone may be established.

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

**'Volunteers'** means GM or non-GM wheat plants which have not been intentionally grown.

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

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



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

## Section 2 General conditions and obligations

3. This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.
4. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMOs are authorised during any period of suspension.
5. The holder of this licence ('the licence holder') is CSIRO.
6. 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.
7. The dealings authorised by this licence are to conduct experiments with the GMOs, propagate, grow, transport, and dispose of the GMOs, and the possession, supply or use of the GMOs in the course of any of these dealings.

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

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

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

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

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

10. The licence holder must:
- (a) inform the Regulator immediately in writing, of:
    - i. any relevant conviction of the licence holder occurring after the issue of this licence; and
    - ii. any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment; and
    - iii. any event or circumstances occurring after the issue of this licence that would affect the capacity of the holder of this licence to meet the conditions in it; and
  - (b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested, within the stipulated timeframe.
11. The licence holder must be able to access and control the Planting Area, Monitoring Zones and Isolation zones, approved facilities and areas requiring Cleaning and/or post-harvest inspections, to the extent necessary to comply with this licence, for the duration of the life of the licence.
- The following conditions seek to ensure that persons conducting the dealings are aware of the licence conditions and appropriate processes are in place to inform people of their obligations.*
12. Prior to conducting any dealings with the GMOs, the licence holder must provide to the Regulator:
- (a) names of all organisations and persons or functions or positions of the persons who will be covered by the licence, with a description of their responsibilities; and  
*Note: Examples of functions or positions are 'project supervisor', 'site manager', 'farm labourer' etc.*
  - (b) detail of how the persons covered by the licence will be informed of licence conditions; and
  - (c) detail of how the licence holder will access and control the Planting Area, Monitoring Zones and Isolation Zones, approved facilities and areas requiring Cleaning and/or post-harvest inspections, for the duration of the licence; and  
*Note: this may include a description of any contracts, agreements, or other enforceable arrangements.*
  - (d) written methodology to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism, and to distinguish between categories of GMOs approved for release; and
  - (e) a Contingency Plan to respond to inadvertent presence of the GMOs outside an area that must be inspected.
13. Any changes to the information provided under the immediately preceding condition must be communicated in writing to the Regulator within 14 days of the changes occurring.
14. The licence holder must inform any person covered by this licence, to whom a particular condition of the licence applies, of the following:
- (a) the particular condition (including any variations of it); and
  - (b) the cancellation or suspension of the licence; and
  - (c) the surrender of the licence.
15. The licence holder must not permit a person covered by this licence to conduct any dealing unless:
- (a) the person has been informed of any applicable licence conditions, including any variation of them; and
  - (b) the licence holder has obtained from the person a signed and dated statement that the person:
    - i. has been informed by the licence holder of the licence conditions including any variation of them; and

ii. has understood and agreed to be bound by the licence conditions, or variation.

16. The licence holder must:

- (a) inform the persons covered by this licence that any Personal Information relevant to the administration and/or enforcement of the licence may be released to the Regulator; and
- (b) provide the Regulator, if requested, with copies of the signed and dated statements referred to in the immediately preceding condition.

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

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

17. The licence holder must inform the Regulator if the licence holder becomes aware of:

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

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

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

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

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

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

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

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

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

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

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

### **Limits on the release**

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

22. The only plants that may be intentionally grown at a Planting Area are:
- (a) the GMOs covered by this licence as described in Attachment A of the licence;
  - (b) non-GM Wheat plants; and
  - (c) plants approved in writing by the Regulator.

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

Location	Maximum size of total Planting Areas per growing season	Maximum number of Planting Areas	Duration
Ginninderra Experiment Station (ACT)	1 ha	Two per growing season	May 2017 – May 2022, inclusive
Boorowa Experiment Station (NSW)	1 ha	Two per growing season	May 2017 – May 2022, inclusive

24. Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals, with the exception of non-viable products derived from Plant Material specified for animal experiments and/or human nutritional experiments.

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

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

then seed produced from the GMOs grown under this licence at the Site must not be used for breeding or propagation to produce cultivars for future commercial release.

#### **Containment measures**

*The following licence conditions maintain the risk assessment context within which the application was assessed by restricting spread and persistence of the GMOs.*

26. The outer edge of the Planting Area must be at least 50 m away from Waterways.

#### **Planting Area**

27. The outer edge of the Planting Area must be surrounded by a Monitoring Zone of at least 10 m maintained in a manner appropriate to allow the identification and/or destruction of Volunteers and Related Species whilst the GMO is growing in the Planting Area until the Planting Area is Cleaned.

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

28. Multiple Planting Areas may be contained within a single Monitoring Zone. The Monitoring Zone must extend 10 m from the outermost edge of all Planting Areas (as indicated in Figure 1).

29. In the Monitoring Zone the only plants which may be grown are GM plants authorised under another licence issued by the Regulator, or plants approved in writing by the Regulator.

30. The Monitoring Zone must be surrounded by an Isolation Zone of 190 m extending from the outer edge of the Monitoring Zone.

31. The GMOs must not be grown in a Planting Area if any crop of Wheat or a Related Species is present within Monitoring Zone or Isolation Zone.
32. The Planting Areas must be inside a fence that is capable of excluding livestock.
33. While the GMOs are growing in a Planting Area, associated areas must be inspected by people trained to recognise Wheat and Related Species, and actions taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
(a) Monitoring Zone	From 14 days prior to the expected commencement of Flowering of any GMOs* until 28 days after all GMOs in the Planting Area have finished Flowering	At least once every 14 days	Volunteers & Related Species	Destroy before Flowering or prevent from Flowering
(b) Isolation Zone	From 14 days prior to the expected commencement of Flowering of any GMOs* until 28 days after all GMOs in the Planting Area have finished Flowering	At least once every 14 days	Volunteers & Related Species	Destroy before Flowering or prevent from Flowering
(c) Fence	While the GMOs are growing	At least once every 35 days	Damage	Repair as soon as possible to maintain exclusion of livestock

*\*Condition 58(a) requires the licence holder to provide information to the Regulator on the expected flowering period, however the inspection period should be based on the observed development of the GMOs, so that inspections commence prior to flowering of any GMOs.*

*Note: Details of any inspection activity must be recorded in a Logbook as detailed in Condition 58.*

#### **Dispersal of GMOs**

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

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

35. Measures must be implemented to control rodents within the Planting Area(s) while GMOs are being grown and until the Planting Area(s) have been Cleaned.

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

36. Non-GM Wheat grown in a Planting Area must be handled as if it were the GMOs.
37. The GMOs must be harvested separately from any other crop.
38. Harvesting must be conducted in a manner so as to avoid dispersal of GMOs outside the Planting Area.
39. 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.
40. If seed harvested from the GMOs is threshed other than in accordance with Notifiable Low Risk Dealings (NLRD) requirements, it must be threshed separately from any other crop, and threshing must take place on the Planting Areas or in a Facility approved in writing by the Regulator.
41. Areas of land and Equipment used in connection with the GMOs must be Cleaned as follows:

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

*Notes: If Tillage is used as a means of Cleaning, it must be conducted in accordance with Condition 55(b). Areas of land that have been cleaned, or from which the GMOs have been harvested, are also subject to inspections (Condition 53). Cleaning activities must be recorded and provided to the Regulator (Condition 58(d)).*

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

*Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 56).*

#### **Experimentation, transport and storage**

43. GMOs not required for experimentation or future planting must be Destroyed as soon as practicable.

44. If GMOs are stored prior to experimentation or Destruction, they must be stored in a Facility within an unbreakable container labelled as containing GMOs or Destroyed as soon as practicable after use.

45. If experimentation with the GMOs, or transport or storage of the GMOs is not conducted in accordance with NLRD requirements, such activities must:

- (a) only occur to the extent necessary to conduct the dealings permitted by this licence or other valid authorisation; and
- (b) be in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* for PC2 GM plant as current at the time of transportation or storage;
- (c) be undertaken within a Planting Area prior to post-harvest Cleaning; or
- (d) be undertaken within a Facility approved in writing by the Regulator; and
- (e) comply with all other conditions of this licence.

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

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

46. Methods and procedures used to transport GMOs must be recorded, and must be provided to the Regulator, if requested.

*Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 56).*

#### **Cleaning**

47. The Planting Area must be Cleaned before the end of the first May following harvesting of the GMOs.

48. If all the GMOs have been Destroyed in the Planting Area, then the area is taken to have been Cleaned for the purposes of this licence and all post-Cleaning conditions will apply.

49. For a Facility, once Cleaning has been completed, the licence holder must send a notification to the Regulator that the Facility has been Cleaned.

50. Cleaning of Equipment must occur as soon as practicable after use and before use for any other purpose.

51. In the case of Equipment used at a Planting Area, the Equipment must be cleaned before it is removed from the area.

#### Conditions relating to Destruction by burial

52. If Destruction of Plant Material occurs by burial, the licence holder must:

- (a) bury Plant Material in a pit into the ground at Ginninderra Experiment Station or Boorowa Experiment Station under this licence ; and
- (b) Plant Material must be buried in such a way that it is covered by a layer of soil at least 1 metre in depth, the top of which is no higher than the soil surface surrounding the burial site; and
- (c) within 14 days of burial, provide the Regulator a written notice indicating the precise location of the burial site (GPS coordinates and either a street address or other directions), the date on which burial occurred and broad description of the Plant Material buried (Planting Area and year the GMOs were planted).

*Note: Other conditions of this Licence require inspections for, and control of, Volunteers at burial sites (condition 53).*

#### Persistence of the GMOs post-Cleaning

53. Post-Cleaning areas of land must be inspected by people trained to recognise Wheat and Related Species. Inspections must cover the entirety of the areas to be inspected. Actions must be taken as follows:

Area of land	Period of inspection	Inspection frequency	Inspect for	Action
(a) Planting Area	From the day of completion of harvest or Destruction of the last Wheat plant in the Planting Area, until: <ul style="list-style-type: none"> <li>i. the area is replanted with the GMOs; or</li> <li>ii. the Regulator has issued a Sign-off for the area.</li> </ul>	At least once every 35 days	Volunteers	Destroy before Flowering
(b) Areas that have been Cleaned (excluding Planting Area)	From the day of Cleaning, until: <ul style="list-style-type: none"> <li>i. the area is replanted with the GMOs; or</li> <li>ii. the Regulator has issued a Sign-off for the area.</li> </ul>	At least once every 35 days	Volunteers	Destroy before Flowering
(c) Fence	From the day of completion of the harvest or Destruction of the last Wheat in the Planting Area, and when livestock are being grazed outside but adjacent to the fence	Each time upon the introduction of livestock and thereafter at least once every 35 days	Damage	Repair as soon as possible to maintain exclusion of livestock
(d) Burial site	From the date of burial until the Regulator has issued a Sign off	At least once every 70 days	Volunteers	Destroy before Flowering

Area of land	Period of inspection	Inspection frequency	Inspect for	Action
			Disturbance of the burial site	Appropriate remedial action; Notify the Regulator of the disturbance and the remedial action taken

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

- (a) date of the inspections;
- (b) name of the person(s) conducting the inspections;
- (c) details of the experience, training or qualification that enables the person(s) to recognise Volunteers, if not already recorded in the logbook;
- (d) details of areas inspected including current land use (including details of any post-harvest crops), presence of livestock and recent management practices applied (including Tillage events);  
*Note: this may also include spraying or maintenance measures used to facilitate inspections for Volunteers.*
- (e) details of the developmental stage of the GMOs while they are being grown;
- (f) details of any post-harvest rainfall events including measurements at or near the area, or any irrigation events;
- (g) details of any damage and any repairs to the fence surrounding the Planting Area and Buffer Zone;
- (h) details of any Volunteers observed during inspections or during land-management activities, including number, developmental stage and approximate position of the Volunteers within each area inspected<sup>⌘</sup>;
- (i) date(s) and method(s) of Destruction of or preventing Flowering of any Volunteers, including destruction of Volunteers during land-management activities; and
- (j) details of rodent control methods used and any evidence of rodent activity.

<sup>⌘</sup> *Examples of acceptable ways to record the positional information for Volunteers in the Logbook include:*

- *descriptive text*
- *marking on a diagram*
- *indicating grid references on corresponding map/sketch*

*Note: Details of Inspection activities must be provided to the Regulator (Condition 58). The Regulator has developed a standardised proforma for recording inspection activities. This can be made available on request.*

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

- (a) the area must be maintained in a manner appropriate to allow identification of Volunteers; and
- (b) any Tillage of the area must be to a depth no greater than the depth of sowing of the GMOs; and  
*Note: delaying the Tillage for at least 28 days following the harvest of the GMOs may promote after-ripening of grain remaining on the soil surface and thereby reduce persistence of seed in the soil, however if conditions are conducive to germination Tillage may be carried out earlier.*
- (c) no plants may intentionally be grown in the area unless the plants are:

- i. the GMOs or non-GM Wheat planted in accordance with the conditions of this licence; or
  - ii. agreed to in writing by the Regulator.
- (d) prior to an application for Sign-off, the area must receive at least three irrigations, at intervals of at least 28 days, with the last required irrigation occurring at a time that would promote the germination of Volunteers within the six month period immediately prior to the Sign-off application; and
- Note: A period of natural rainfall may be taken as irrigation only with the agreement of the Regulator. Evidence (such as rainfall measurements, photos etc.) that the rainfall has been sufficient to promote germination should be provided.*
- (e) prior to the final irrigation referred to in the immediately preceding condition, the area must be Tilled.

### **Contingency plan**

56. If any unintentional presence of the GMOs is detected outside the areas requiring inspection, the Contingency Plan must be implemented.

## **Section 4 Sign off**

57. The licence holder may make written application to the Regulator that planting restrictions and inspection requirements no longer apply to the Planting Area if:

- (a) all post-Harvest or post-Cleaning inspection activities have been conducted for at least 24 months on the area
- (b) conditions have been conducive for germination and detection; and
- (c) no Volunteers have been detected on this area in the most recent six month inspection period.

*Note: The Regulator will take into account the management and inspection history for the Planting Area and associated areas, including post-harvest crops planted (if any), Tillage, irrigation, rainfall, application of herbicide and occurrence of volunteers, in deciding whether or not further inspections are required to manage persistence of the GMOs.*

## **Section 5 Reporting and Documentation**

*The following licence conditions are imposed to demonstrate compliance with other conditions, facilitate monitoring of compliance by staff of the OGTR, and emphasise appropriate selection of the Planting Area.*

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

Notice	Content of notice	Timeframe
(a) Intention to Plant	<ul style="list-style-type: none"> <li>i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the sites (eg Google Maps) and any other descriptions</li> <li>ii. Identity of the GMOs to be planted at the Planting Area (eg lines or construct details)</li> <li>iii. Date on which the GMOs will be planted</li> <li>iv. Period when the GMOs are expected to Flower</li> <li>v. Period when harvesting is expected to commence</li> <li>vi. How all areas requiring post-harvest inspections are intended to be used until sign-off, including the proposed post-harvest crop(s) (if any)</li> <li>vii. Details of how you propose to manage inspection activities, including strategies for the detection and destruction of volunteer GMOs</li> <li>viii. If GMOs have previously been planted at the Planting Area, a history indicating how the Planting Area has been used in the preceding 2 years, including details of previous GMOs and post-harvest crops planted</li> </ul>	At least 7 days prior to each planting (to be updated immediately if the notified details change)
(b) Planting	<ul style="list-style-type: none"> <li>i. Actual date(s) of planting the GMOs</li> <li>ii. Any changes to the details provided under part (a) of this condition.</li> </ul>	Within 7 days of any planting
(c) Harvest	<ul style="list-style-type: none"> <li>i. Actual date(s) of harvesting the GMOs.</li> </ul>	Within 7 days of commencement of any harvesting
(d) Cleaning	<ul style="list-style-type: none"> <li>i. Actual date(s) on which any areas needing Cleaning were Cleaned.</li> <li>ii. Method of Cleaning</li> </ul>	Within 7 days of completion of any Cleaning
(e) Burial	<ul style="list-style-type: none"> <li>i. Actual date(s) of Burial</li> <li>i. Broad description of the Plant Material buried (Condition 52)</li> </ul>	Within 14 days of any burial
(f) Inspection activities	<ul style="list-style-type: none"> <li>i. Information recorded in a Logbook as per the inspection requirements (Conditions 33, 53 and 54).</li> </ul>	Within 35 days of inspection

*Note: Other reports and documents that may need to be sent to the Regulator are listed in Attachment B*

**DIR No: 151**

**Full Title:** Limited and controlled release of wheat genetically modified for disease resistance, drought tolerance, altered oil content and altered grain composition

### **Organisation Details**

Postal address: CSIRO  
GPO Box 1700  
Acton  
ACT 2601

Phone No: (02) 6246 5032

### **IBC Details**

IBC Name: IBC 103 (CSIRO Agriculture and Food Biosafety Committee)

### **GMO Description**

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

Wheat plants genetically modified by introduction of only the genes or genetic elements listed below

#### **Parent Organism:**

Common Name: Wheat

Scientific Name: *Triticum aestivum* L.

#### **Modified traits:**

Categories: Disease resistance  
Abiotic stress tolerance  
Composition – food (processing)  
Composition – food (human nutrition)  
Selectable marker – antibiotic resistance

Description: Wheat plants have been genetically modified have been genetically modified for:

- resistance to leaf rust, stripe rust and stem rust
- tolerance to abiotic stresses
- altered starch metabolism
- increased oil content
- altered grain dietary fibre content

by introduction of one to three of the genes listed in Table 1 with associated regulatory sequences listed in Table 2.

**Table 1. Genes introduced in the GM wheat lines**

Gene	Full name and description	Source	Intended function	
<i>Lr67</i>	Sugar transporter gene variant	<i>Triticum aestivum</i>	Multi-pathogen resistance	
<i>Lr46</i>	Slow anion channel like gene	<i>Triticum aestivum</i>		
<i>Lr34</i>	ABC transporter gene variant	<i>Triticum aestivum</i>		
<i>Yr36</i>	Kinase-lipid binding protein	<i>Triticum turgidum</i> ssp <i>dicoccoides</i>	Stripe rust resistance	
<i>Lr21</i>	Nucleotide binding leucine rich repeat	<i>Aegilops tauschii</i>	Leaf rust resistance	
<i>Sr46</i>	Nucleotide binding leucine rich repeat	<i>Aegilops tauschii</i>	Stem rust resistance	
<i>Sr2-PMP3</i>	Putative transmembrane protein	<i>Triticum aestivum</i>	Potential stem rust resistance	
<i>Sr2-D8LAL2</i>	Putative transmembrane protein	<i>Triticum aestivum</i>		
<i>Sr2-GLP1_2</i>	Putative transmembrane protein	<i>Triticum aestivum</i>		
<i>TaCAT1</i>	Calcium binding protein	<i>Triticum aestivum</i>	Accumulation of stem carbon reserves	
<i>TaNf-YA7</i>	Transcription factor	<i>Triticum aestivum</i>		
<i>TaNAC69</i>	Transcription factor	<i>Triticum aestivum</i>	Regulation of drought stress response genes, modification of root architecture	
<i>HvCBF1</i>	Transcription factor	<i>Hordeum vulgare</i>		
<i>TaZFP34</i>	Transcription factor	<i>Triticum aestivum</i>		
<i>TaHsfC2a</i>	Transcription factor	<i>Triticum aestivum</i>		
<i>TaHfsA6f</i>	Transcription factor	<i>Triticum aestivum</i>		
<i>TaRNAC1</i>	Transcription factor	<i>Triticum aestivum</i>		
<i>TaNAC2</i>	Transcription factor	<i>Triticum aestivum</i>		
<i>TaHsfC2d</i>	Transcription factor	<i>Triticum aestivum</i>		
<i>TaHsfC1e</i>	Transcription factor	<i>Triticum aestivum</i>		
<i>TaMYB20</i>	Transcription factor	<i>Triticum aestivum</i>		
<i>TaWRKY17</i>	Transcription factor	<i>Triticum aestivum</i>		
<i>AMY1</i>	Alpha-amylase 1	<i>Triticum aestivum</i>		Altered starch metabolism
<i>AMY2</i>	Alpha-amylase 2	<i>Triticum aestivum</i>		
<i>AMY3</i>	Alpha-amylase 3	<i>Triticum aestivum</i>		
<i>ZmWRI1</i>	Transcription factor (Wrinkled 1)	<i>Zea mays</i>	Enhanced oil accumulation	
<i>UrDGAT2a</i>	Diacylglycerol acyltransferase	<i>Umbelopsis ramanniana</i>		
<i>AtDGAT1</i>	Diacylglycerol acyltransferase 1	<i>Arabidopsis thaliana</i>		
<i>SinOLEOSIN</i>	Oleosin	<i>Sesamum indicum</i>		
<i>AsCsIF6</i>	Cellulose synthase like F6 gene	<i>Avena sativa</i>	Altered dietary fibre content	
<i>BdCsIF6</i>	Cellulose synthase like F6 gene	<i>Brachypodium distachyon</i>		
<i>HvCsIF6</i>	Cellulose synthase like F6 gene	<i>Hordeum vulgare</i>		
<i>ZmCsIF6-1</i>	Cellulose synthase like F6 gene 1	<i>Zea mays</i>		
<i>ZmCsIF6-2</i>	Cellulose synthase like F6 gene 2	<i>Zea mays</i>		
<i>OsCsIF6</i>	Cellulose synthase like F6 gene	<i>Oryza sativa</i>		
<i>SbCsIF6</i>	Cellulose synthase like F6 gene	<i>Sorghum bicolor</i>		
<i>BdCsIH</i>	Cellulose synthase like H gene	<i>Brachypodium distachyon</i>		

**Table 2. Regulatory genetic elements introduced into the GM wheat lines**

Genetic element	Description	Source
<b>Promoters (genes of interest)</b>		
<i>pLr67</i>	Native promoter from the Lr67 gene	<i>Triticum aestivum</i>
<i>pLr46</i>	Native promoter from the Lr46 gene	<i>Triticum aestivum</i>
<i>pLr34</i>	Native promoter from the Lr34 gene	<i>Triticum aestivum</i>
<i>pYr36</i>	Native promoter from the Yr36 gene	<i>Triticum turgidum ssp dicoccoides</i>
<i>pLr21</i>	Native promoter from the Lr21 gene	<i>Aegilops tauschii</i>
<i>pSr46</i>	Native promoter from the Sr46 gene	<i>Aegilops tauschii</i>
<i>pUbi1</i>	Promoter from ubiquitin 1 gene	<i>Zea mays</i>
<i>pRSP3</i>	Root specific promoter from RSP3 gene	<i>Oryza sativa</i>
<i>pDhn8s</i>	Constitutive promoter with strong expression in roots and leaves, from Dhn8s gene	<i>Hordeum vulgare</i>
<i>pPR1L2</i>	Root specific promoter, from PR1L2 gene	<i>Oryza sativa</i>
<i>pPIP2;3</i>	Root specific promoter, from PIP2;3 gene	<i>Oryza sativa</i>
<i>pGRP7</i>	Root specific promoter, from GRP7 gene	<i>Oryza sativa</i>
<i>pBx17</i>	Grain endosperm specific promoter from glutenin gene Bx17	<i>Triticum aestivum</i>
<i>pLPT2</i>	Aleurone specific promoter from LPT2 gene	<i>Triticum aestivum</i>
<i>pOsAct1</i>	Promoter from Actin 1 gene	<i>Oryza sativa</i>
<i>pZmSSU</i>	Promoter from Rubisco small subunit gene	<i>Zea mays</i>
<i>pBdGLU1</i>	Promoter from glutenin gene GLU1	<i>Brachypodium distachyon</i>
<i>pOsGLU4</i>	Promoter from glutenin gene GLU4	<i>Oryza sativa</i>
<i>pOsGLUB</i>	Promoter from glutenin gene GLUB5	<i>Oryza sativa</i>
<i>pOsGLUC</i>	Promoter from glutenin gene GLUC	<i>Oryza sativa</i>
<i>pTaPinA</i>	Promoter from the purindoline A gene	<i>Triticum aestivum</i>
<i>pTaPinB</i>	Promoter from the purindoline B gene	<i>Triticum aestivum</i>
<b>Promoters (antibiotic resistance markers)</b>		
<i>35S</i>	Promoter used for resistance markers	<i>Cauliflower mosaic virus</i>
<i>e-35S</i>	Promoter used for resistance markers	<i>Cauliflower mosaic virus</i>
<i>pCmYLCV</i>	Promoter used for resistance markers	<i>Cestrum yellow leaf clearing virus</i>
<b>Terminators</b>		
<i>Ocs 3'</i>	3' non translated region of the octopine synthase	<i>Agrobacterium tumefaciens</i>
<i>RbcS 3'</i>	3' non translated region of the Rubisco small subunit gene	<i>Triticum aestivum</i>
<i>Nos 3'</i>	3' non translated region of the nopaline synthase gene	<i>Agrobacterium tumefaciens</i>
<i>CaMVpolyA</i>	Terminator	<i>Cauliflower mosaic virus</i>
<b>Introns</b>		
<i>STLS1</i>	Intron inserted in resistance marker sequence	<i>Solanum tuberosum</i>
<i>Intron 1 cat</i>	Intron used in RNAi construct	<i>Ricinus communis</i>
<i>Intron 3 pdk</i>	Intron used in RNAi construct	<i>Flaveria trinervia</i>
<i>Rint 4</i>	Intron used in RNAi construct	<i>Oryza sativa</i>
<i>Rint 9</i>	Intron used in RNAi construct	<i>Oryza sativa</i>

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

The purpose of the trial is to evaluate the agronomic performances of the GM wheat under Australian field conditions. For wheat lines with genetically modified grain composition, another purpose of this trial is to analyse changes in nutritional characteristics, dough making properties and end product quality. Flour derived from the grain of GM wheat lines with altered grain composition is proposed to be used for a range of carefully controlled, small scale animal and human nutritional trials under the oversight of CSIRO Human Nutrition Animal Ethics Committee and CSIRO Human Nutrition Research Ethics Committee, respectively. The GM wheat lines are not permitted to enter the commercial human food or animal feed supply chains.

## ATTACHMENT B

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

When	What	Condition	Timeframe of reporting
Prior to conducting any dealings	Details of persons covered	12(a)	
	Plan to inform people covered by the licence	12(b)	
	Plan to ensure control and access to the Site	12(c)	
	Detection methodology	12(d)	
	Contingency plan	12(e)	
Prior to planting	Intention to Plant at the Planting Area	58(a)	At least 7 days prior to each planting
Planting	Planting at the Planting Area	58 (b)	Within 7 days of any planting
While growing	Fence inspections	33 (c)	At least once every 35 days
	Monitoring Zone and Isolation Zone inspections during Flowering	33 (a)	At least every 14 days
After harvest	Harvesting at the Planting Area	58 (c)	Within 7 days of commencement of any harvesting
Post-Cleaning	Cleaning	58 (d)	Within 7 days of completion
	Burial	52	Within 14 days of any burial
	Post-harvest inspections	53	Within 35 days of each inspection
Any time after issue of the licence	Any changes of the project supervisor contact details	8	As soon as practicable
	Any relevant conviction, revocation, suspension or cancellation of any relevant permit or circumstances that may affect compliance to licence conditions	10 (a)	Immediately, if occurs
	Any information relevant to on-going suitability	10(b)	If and when requested
	Any changes to details provided under conditions 12(a) - 12(e)	13	Within 14 days of the changes
	Signed statements from persons covered under the licence	16(b)	If and when requested
	Any additional information regarding health and safety of the people and the environment, contraventions of this licence or any unintended effects of the dealings authorized by the licence	17	Without delay, after becoming aware
	Extreme weather conditions	42	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport	46	If and when requested