



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 162

Licence holder: CSIRO

Title: Limited and controlled release of bread wheat and durum wheat genetically modified for enhanced rust disease resistance

Issued: 11 July 2018

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

Gene Technology Regulation in Australia

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

2. In this licence:

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

'Burial Site' means a place where the GMOs are buried for purposes of destruction.

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

- a. in relation to an area specified in this licence as requiring Cleaning, the Destruction of the GMOs 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 to the reasonable satisfaction of the Regulator; and
- c. inspect for and Destroy any Volunteers that may exist as a result of the event to the reasonable satisfaction of the Regulator.

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

- a. uprooting;
- b. tilling, but only subject to the conditions of this licence;
- c. treatment with herbicide;
- d. burning/incineration;
- e. autoclaving;
- f. 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, footwear and tools.

'Extreme Weather' includes, but is not limited to, fires, flooding, cyclones, earthquakes or torrential rain, that could disperse GMOs.

'Facility' a 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.

'Inspection Zone' means an area of land extending 50 m in all directions from the outer edge of the Monitoring Zone as indicated in Figure 1.

'Isolation Zone' means an area of land extending 140 metres in all directions from the outer edge of the Inspection Zone as indicated in Figure 1.

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

'Monitoring Zone' means an area of land extending outwards at least 10 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 or opinion is true or not; and
- b. Whether the information or opinion 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, or any product of these plants.

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

'Regulator' means the Gene Technology Regulator.

'Related Species' means plants from the genus *Triticum*, excluding bread wheat and durum wheat.

'Sign-off' means a notice in writing from the Regulator, in respect of an area, that post-Cleaning 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 *Triticum aestivum* L. em Thell (bread wheat) or *Triticum turgidum* subsp. *durum* (Desf.) Husn (durum wheat).

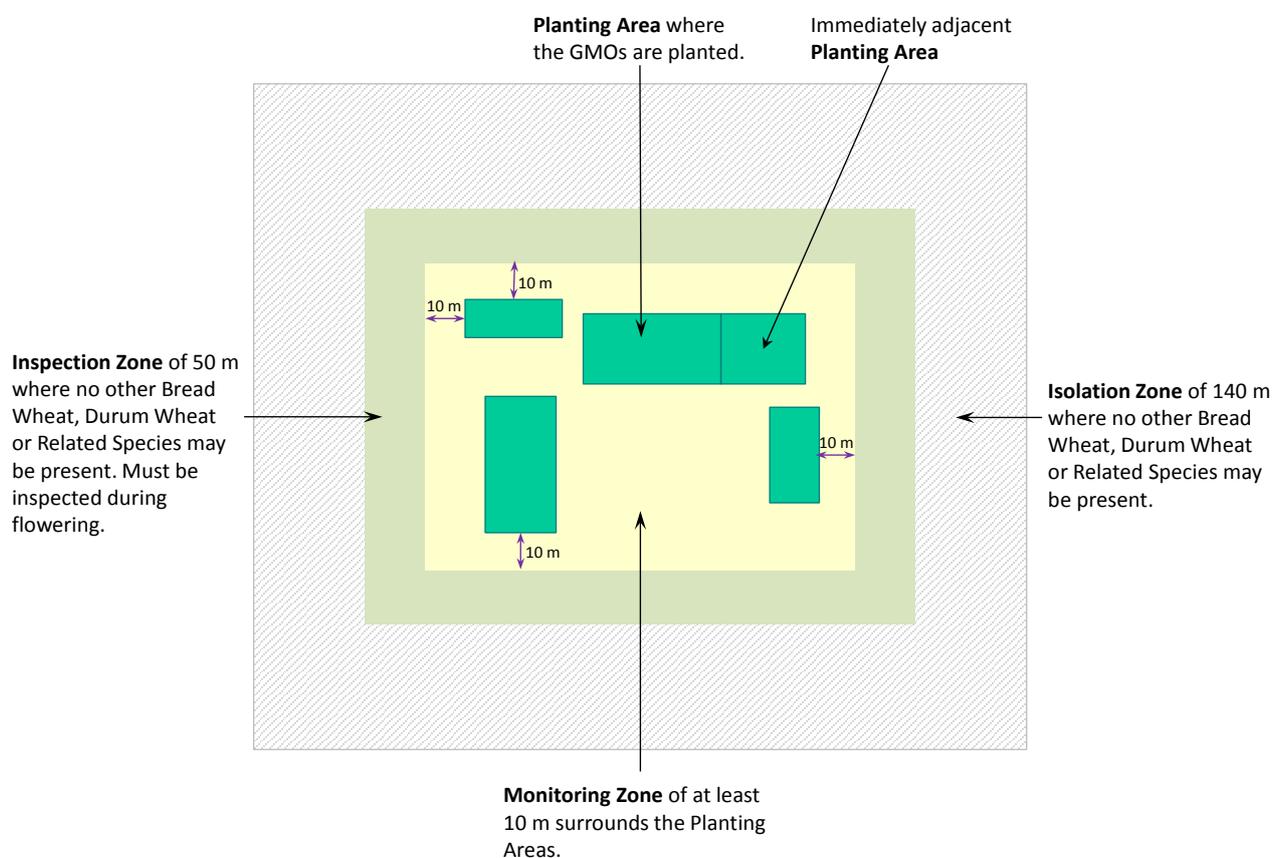


Figure 1 Diagram (not to scale) showing the relationship between Planting Area, Monitoring Zone, Inspection Zone and Isolation Zone.

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, breed, propagate, grow, transport and dispose of the GMOs, and 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.

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

9. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and must comply with its instrument of accreditation.
10. The licence holder must:
 - a. inform the Regulator immediately in writing, of:
 - i. any relevant conviction of the licence holder occurring after the commencement of this licence; and
 - ii. any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment; and
 - iii. any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it; and
 - b. provide any information related to the licence holder's ongoing suitability to hold a licence, if requested, within the stipulated timeframe.
11. The licence holder must be able to access and control the Planting Areas, Monitoring Zones, Inspection Zones, Isolation Zones, Burial Sites and approved Facilities to the extent necessary to comply with this licence, for the duration 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, Inspection Zones, Isolation Zones and approved Facilities, for the duration of the licence; and
Note: this may include a description of any contracts, agreements, or other enforceable arrangements.
 - d. written methodology to reliably detect the GMOs 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 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 and 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 2 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:
- the GMOs covered by this licence as described in Attachment A of the licence;
 - non-GM Wheat plants; and
 - plants approved in writing by the Regulator.
23. Planting and growing of the GMOs may only occur within the following limits:
- up to two Sites per season for the release of GM Wheat lines, as listed in the table below:

Location	Maximum total ^a size of Planting Areas per growing season	Duration
Ginninderra Experiment Station (ACT)	1 ha	From issue of licence until 30 September 2023
Boorowa Experiment Station (NSW)		

^a Total area permitted for planting across both locations.

- for each Site, more than one planting area may be established each season
24. Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals.
25. If GM plants, other than the GMOs authorised by this licence, are:
- grown under another licence within the Site at a time when the GMOs authorised by this licence are also being grown; and
 - sexually compatible with the GMOs authorised by this licence;

then information about all lines grown concurrently must be reported to the Regulator in accordance with conditions 61.a.vi/61.b.iii.

Note: This information may also be required to be provided for related future licence applications.

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.

Cultivation of the GMOs

27. The outer edge of the Planting Area must be surrounded by a Monitoring Zone of at least 10 m. The Monitoring Zone must be 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 cm.

28. Non-GM Wheat plants grown in a Planting Area must be handled as if they were the GMOs.

29. Multiple Planting Areas may be contained within a single Monitoring Zone. No Planting Area may be less than 10 m from the outer edge of the Monitoring Zone (as indicated in Figure 1).

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

31. The Monitoring Zone must be surrounded by an Inspection Zone (as indicated in Figure 1).

32. The Inspection Zone must be surrounded by an Isolation Zone (as indicated in Figure 1).

33. The GMOs must not be grown in a Planting Area if any crop of Wheat or a Related Species is present within the Inspection Zone or Isolation Zone.

34. While the GMOs are growing in a Planting Area, associated areas must be inspected by people trained to recognise Bread Wheat, Durum 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. Inspection Zone				

**Condition 61.a.iv 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 61.f.

Dispersal of GMOs

35. Measures must be implemented to control rodents within the Planting Area 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 baits within and/or surrounding the Planting Area.

36. 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.

37. The GMOs must be harvested separately from any other crop.

38. Harvesting must be conducted in a manner that avoids 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.

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. The licence holder must notify the Regulator in writing as soon as reasonably practicable of any Extreme Weather Event that could cause or has led to the dispersal of GMOs from a Planting Area while the GMOs are growing or from any area subject to Cleaning and Inspection requirements.

Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 59).

Processing or experimentation with GMOs

42. If processing of GM seed or experimentation or analysis with the GMOs is not conducted under a Notifiable Low Risk Dealings (NLRD) authorisation, such activities may only be undertaken within:

- a. a Planting Area; or
- b. a Facility approved in writing by the Regulator.

Note: Dealings conducted under a NLRD authorisation must be assessed by an Institutional Biosafety Committee before commencement, must comply with the requirements of the Regulations, and are not subject to the conditions of this licence.

43. Within a Facility approved under the preceding conditions, any area that is used for threshing, processing, experimentation or analysis of the GMOs must be Cleaned as soon as practicable and before use for any other purpose.

44. GMOs not required to conduct experiments or for planting under this licence must be Destroyed as soon as practicable.

Dispersal of the GMOs during transport or storage

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

46. If 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 ; and
- c. 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.

47. 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 59).

Cleaning

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

49. 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.

50. While post-Cleaning inspection requirements apply to the Planting 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 volunteer-free period immediately prior to the Sign-off application; and

Note: A period of natural rainfall (as recorded in condition 58.f) may be taken as irrigation only with the agreement of the Regulator. Evidence (such as rainfall measurements, photos of germinating plants 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.

51. Any area outside the Planting Area where the GMOs have been dispersed in the course of dealings under this licence, must be Cleaned as soon as practicable and before use for any other purpose.

Notes: This would include, but is not limited to approved Facilities, areas used to Clean Equipment.

Notes: Areas of land that have been Cleaned are subject to inspections (Condition 57). Cleaning activities must be recorded and provided to the Regulator (Condition 61.d).

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

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

54. 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 c. any Equipment used in connection with the GMOs d. any area used to Clean any Equipment used in connection with the GMOs e. any area used to experiment with, analyse or store GMOs	As soon as practicable and before use for any other purpose

Note: If Tillage is used as a means of Cleaning, it must be conducted in accordance with Condition 50.b. Areas of land that have been Cleaned, or from which the GMOs have been harvested, are also subject to Inspections (Condition 57). Cleaning activities must be recorded and provided to the Regulator (Condition 61.d).

Note: If GM seeds have been dispersed around the burial pit during burial, this area will require cleaning under condition 54, and post-cleaning licence conditions will apply.

Conditions relating to Destruction by burial

55. Burial must be conducted in a manner that minimises the likelihood of dispersal of GMOs outside the Burial Site.
56. If Destruction of Plant Material occurs by burial:
- a. the GMOs must be buried in a pit dug into the ground in such a way that the GMOs are covered by a layer of soil at least 1 m in depth, the top of which is no higher than the soil surface surrounding the Burial Site; and
 - b. Plant Material may be buried as specified in 56.a at Boorowa Agricultural Research Station only;
 - c. seeds must be sufficiently irrigated at time of burial to encourage decomposition;
 - d. 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 description of the GMOs buried (Planting Area and year the GMOs were planted);
 - e. the Burial Site must not be intentionally disturbed for a period of at least 12 months from the date of burial; and
 - f. the Burial Site must be inspected during this period to identify any significant disturbance. If disturbance is identified, the licence holder must take appropriate remedial action and notify the Regulator of the disturbance and the remedial action taken.

Note: Results of inspection activities are required to be recorded in a Logbook and provided to the Regulator (Condition 61.e).

The licence cannot be surrendered until Burial Site conditions have been satisfied.

Persistence of the GMOs post-Cleaning

57. Post-Cleaning areas of land must be inspected by people trained to recognise Bread Wheat or Durum Wheat. 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
Planting Area or other areas that have been Cleaned	From the day of completion of harvest of the last Wheat plant in the Planting Area, until: i. the area is replanted with the GMOs; or ii. the Regulator has issued a Sign-off for the area.	At least once every 35 days	Volunteers	Destroy before Flowering

58. 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 Volunteers observed during inspections or during land-management activities, including number, developmental stage and approximate position of the Volunteers within each area inspected[†];
- h. date(s) and method(s) of Destruction of or preventing Flowering of any Volunteers, including destruction of Volunteers during land-management activities; and
- i. details of rodent control methods used and any evidence of rodent activity.

[†] 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 61). The Regulator has developed a standardised proforma for recording inspection activities. This can be made available on request.

Contingency plan

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

Section 3 Sign off

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

- a. all 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 for at least six months of the inspection period immediately prior to the Sign off request.

Note: A Planting Area and the aggregate of all other areas of land requiring Cleaning will be signed-off as a group rather than individually. Licence conditions require a Tillage event and three irrigations prior to a Sign-off application (see Conditions 50.d and 50.e).

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 4 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.

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

Notice	Content of notice	Timeframe
a. Intention to Plant	i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the trial sites (e.g. Google Maps) and any other descriptions. If the Planting Area is on an area from DIR 151 that is not signed off, you must state this in the notification	At least 7 days prior to each planting (to be updated immediately if the notified details change)

Notice	Content of notice	Timeframe
	<ul style="list-style-type: none"> ii. Identity of the GMOs to be planted at the Planting Area (e.g. lines or construct details) iii. Date on which the GMOs will be planted iv. Period when the GMOs are expected to Flower v. Period when harvesting is expected to commence vi. Details of all sexually compatible lines being grown concurrently at the Site under any other licence. vii. How all areas requiring post-Cleaning inspections are intended to be used until sign-off, including the proposed post-harvest crop(s) (if any) viii. Details of how you propose to manage inspection activities, including strategies for the detection and destruction of volunteer GMOs ix. History of how the site has been used for the previous two years 	
b. Planting	<ul style="list-style-type: none"> i. Actual date(s) of planting the GMOs ii. Any changes to the details provided under part (a) of this condition iii. Details of all sexually compatible lines being grown concurrently at the site under any other licence, if not previously notified (62.a.vi). 	Within 7 days of any planting
c. Harvest	<ul style="list-style-type: none"> i. Actual date(s) of harvesting the GMOs 	Within 7 days of commencement of any harvesting
d. Cleaning	<ul style="list-style-type: none"> i. Actual date(s) on which any areas needing Cleaning were Cleaned ii. Method of Cleaning 	Within 7 days of completion of any Cleaning
e. Burial	<ul style="list-style-type: none"> i. Actual date(s) and precise location of Burial ii. Description of the GMOs buried (Condition 56.d) iii. Record of any disturbance to the Burial Site and remedial actions taken iv. Record of any Volunteers observed at the Burial site and details of Destruction 	<p>Within 14 days of any burial</p> <p>As soon as practicable</p> <p>Within 7 days of completion of any Cleaning</p>
f. Inspection activities	<ul style="list-style-type: none"> i. Information recorded in a Logbook as per the inspection requirements (Conditions 34, 57 and 58). 	Within 35 days of Inspection

DIR No: 162

Full Title: Limited and controlled release of bread wheat and durum wheat genetically modified for enhanced rust disease resistance

Organisation Details

Postal address: CSIRO
GPO Box 1700
Acton, ACT
2601

Phone No: 02 6246 4001

IBC Details

IBC Name: CSIRO Agriculture and Food Biosafety Committee (IBC103)

GMO Description

GMOs covered by this licence:

Bread wheat and durum wheat plants genetically modified by introduction of only the genes or genetic elements listed below

Parent Organisms:

Common Name: Bread wheat and durum wheat

Scientific Name: *Triticum aestivum* L. and *Triticum turgidum* subsp. *durum*.

Modified traits:

Categories: Enhanced rust disease resistance
Selectable marker – antibiotic resistance

Description: Wheat¹ plants have been genetically modified for enhanced rust disease resistance with the introduction of between one and eight genes for stem rust resistance, in some lines combined with a single gene for multi-pathogen (stem, leaf and streak rusts and powdery mildew) resistance, or single genes for multi-pathogen resistance as listed in Table 1. Associated regulatory sequences for the genes are listed in Table 2.

Purpose of the dealings with the GMOs:

The purpose of the trial is to evaluate the rust disease resistance and agronomic performance of the GM Wheat under Australian field conditions.

Subject to any conditions imposed by DIR 151, this licence does not prohibit the planting of GMOs authorised under this licence on Planting Areas previously used for DIR 111 and DIR 151 or adjacent to Planting Areas concurrently planted under DIR 151.

The GM Wheat is not permitted to be used for human food or animal feed.

¹ The term 'wheat' will be used to include both bread wheat and durum wheat where possible. Where reference is made to either species separately they will be identified as bread wheat (*T. aestivum*) or durum wheat (*T. turgidum* subsp. *durum*).

Table 1. Genes introduced in the GM wheat lines

Gene	Gene Source	Description
<i>Stem rust resistance genes</i>		
<i>Sr50</i>	<i>Secale cereale</i>	Nucleotide binding leucine rich repeat sequence
<i>Sr45</i>	<i>Aegilops tauschii</i>	Nucleotide binding leucine rich repeat sequence
<i>Sr22</i>	<i>Triticum monococcum</i> subsp. <i>aegilopoides</i>	Nucleotide binding leucine rich repeat sequence
<i>Sr35</i>	<i>Triticum monococcum</i>	Nucleotide binding leucine rich repeat sequence
<i>Sr46</i>	<i>Aegilops tauschii</i> ^a	Nucleotide binding leucine rich repeat sequence
<i>Sr26</i>	<i>Triticum aestivum</i>	Nucleotide binding leucine rich repeat sequence
<i>Sr33</i>	<i>Aegilops tauschii</i>	Nucleotide binding leucine rich repeat sequence
<i>Sr33m</i>	<i>Aegilops tauschii</i>	Nucleotide binding leucine rich repeat sequence
<i>Multi-pathogen resistance genes</i>		
<i>Lr67</i>	<i>Triticum aestivum</i>	Sugar transporter gene variant
<i>Lr34</i>	<i>Triticum aestivum</i>	ABC transporter variant
<i>Lr34B</i>	<i>Triticum aestivum</i>	Homologue of <i>Lr34</i>

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

Genetic element	Gene Source	Description
<i>Promoters</i>		
<i>35S</i>	Cauliflower mosaic virus	Promoter for resistance markers
<i>pSr50</i>	<i>Secale cereale</i>	Native promoter from the <i>Sr50</i> gene
<i>pSr45</i>	<i>Aegilops tauschii</i>	Native promoter from the <i>Sr45</i> gene
<i>pSr22</i>	<i>Triticum monococcum</i> subsp. <i>aegilopoides</i>	Native promoter from the <i>Sr22</i> gene
<i>pSr35</i>	<i>Triticum monococcum</i>	Native promoter from the <i>Sr35</i> gene
<i>pSr46</i>	<i>Aegilops tauschii</i>	Native promoter from the <i>Sr46</i> gene
<i>pSr26</i>	<i>Triticum aestivum</i>	Native promoter from the <i>Sr26</i> gene
<i>pSr33</i>	<i>Aegilops tauschii</i>	Native promoter from the <i>Sr33</i> gene
<i>pLr67</i>	<i>Triticum aestivum</i>	Native promoter from the <i>Lr67</i> gene
<i>Introns</i>		
<i>Stls1 I2</i>	<i>Solanum tuberosum</i>	Intron inserted in resistance marker sequence
<i>Selectable Marker Genes</i>		
<i>hptII</i>	<i>Streptomyces hygroscopicus</i>	Plant selectable marker - hygromycin resistance
<i>bar</i>	<i>Streptomyces hygroscopicus</i>	Plant selectable marker - glufosinate herbicide resistance
<i>nptII</i>	<i>Escherichia coli</i> K12	Plasmid selectable marker - kanamycin resistance
<i>Terminators</i>		
<i>CaMVpolyA</i>	Cauliflower mosaic virus	Terminator
<i>OCS</i>	<i>Agrobacterium tumefaciens</i>	3' non-translated region of the octopine synthase gene

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	61.a	At least 7 days prior to each planting
Planting	Planting at the Planting Area	61.b	Within 7 days of any planting
While growing	Monitoring Zone and Inspection Zone inspections during Flowering	34.a; 34.b	At least every 14 days
After harvest	Harvesting at the Planting Area	61.c	Within 7 days of commencement of any harvesting
Post-Cleaning	Cleaning	61.d	Within 7 days of completion
	Burial	56.d; 61.e	Within 14 days of any burial
	Post-cleaning inspections	57	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	41	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport	47	If and when requested