



**Australian Government**  
**Department of Health and Ageing**  
**Office of the Gene Technology Regulator**

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

Licence No: DIR 053/2004

Licence Holder: Grain Biotech Australia Pty Ltd

Title: Field trial of genetically modified salt tolerant wheat (*Triticum aestivum* L.) on saline land

Issued: 21 April 2005

Varied: 21 June 2005

**More information about this licence is contained in the risk assessment and risk management plan prepared in connection with this 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**

The *Gene Technology Act 2000* (Cth) and corresponding State and Territory legislation form a substantial part of a range of integrated regulatory measures relevant to controlling genetically modified organisms (GMOs) and their use.

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

### **Note in relation to approval of genetically modified foods for human consumption**

Food Standards Australia New Zealand (FSANZ) is responsible for human food safety assessment. FSANZ approval would need to be obtained before the GM wheat could be used as human food. This licence contains a condition that prohibits this use.

### **Note about where the GMOs are being planted pursuant to this licence**

Information about where the GMOs are being planted pursuant to this licence can be found in a separate document entitled 'DIR053/2004 Site Details'. This document can be viewed by accessing the document directly at <http://www.ogtr.gov.au/ir/dir053.htm> or clicking here.

## SECTION 1 INTERPRETATION AND DEFINITIONS

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.

In this licence:

- (a) 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) and equivalent provisions in corresponding State law;

**‘Annual Report’** means a written report provided to the Regulator within 90 days of each anniversary of this licence containing all the information required by this licence to be provided in the Annual Report.

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

- (a) in relation to a Location or other area, the Destruction of the GMOs and Plant Material in that Location or area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs and Plant Material from the Equipment, to the reasonable satisfaction of the Regulator;

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

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

*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 killing the remains of harvest of the GMOs, treatment of post harvest remains by herbicide would not be a sufficient mechanism.*

**'Equipment'** includes harvesters, seeders, storage equipment, transport equipment (e.g. bags, containers, trucks), clothing and tools;

**'GM'** means genetically modified;

**'GMOs'** means the genetically modified organism or organisms authorised for release by this licence;

**'Isolation Zone'** means the area of land, extending outwards 500 metres in all directions from the outer edge of the area of land where the GMOs are planted and grown;

**'Location'** means the area of land where the GMOs are planted and grown;

**'Monitoring Zone'** means the area of land, extending outwards 10 metres in all directions from the outer edge of the area of land where the GMOs are planted and grown.

**'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;

**'Plant Material'** means viable parts of GMOs, including seed, stubble, pollen, whether from the plant itself or derived from or produced by the plant;

**'Reference Cereal'** means non-genetically modified *Triticum aestivum* planted in a Location for the purpose of agronomic comparisons.

**'Regulator'** means the Gene Technology Regulator;

**‘Related Species’** means plants in the genera *Triticum*, *Hordeum*, *Secale*, *Aegilops*, *Elytrigia*;

**‘Sign-off’** means a notice in writing from the Regulator, in respect of a place, that post harvest inspection conditions no longer apply in respect of that place;

**‘Triticum population’** means groups of 5 or more plants per square metre of land belonging to the genera *Triticum*, *Secale*, *Triticale*;

**‘Volunteer plants’** means progeny of the GMOs or regrowth of previous GM or non-GM wheat.

## **SECTION 2 GENERAL CONDITIONS**

### **Duration of Licence**

1. 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**

2. The holder of this licence ('the licence holder') is Grain Biotech Australia Pty Ltd.

### **Project Supervisor**

3. The Project Supervisor in respect of this Licence is identified at Attachment A\*.
4. The licence holder must immediately notify the Regulator in writing if any of the contact details of the Project Supervisor change.

### **No dealings with GMOs except as authorised by this licence**

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

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

6. The GMOs covered by this licence are described at Attachment B\*.

### **Permitted dealings**

7. The permitted dealings with the GMOs are to plant, grow and conduct experiments with the GMOs, and the possession, supply, use, transport and disposal of the GMOs for the purpose of any of the permitted dealings with the GMOs, or in the course of any of these dealings.

### **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 to undertake any activity in connection with GMOs grown in a Location pursuant to this Licence.

### **Informing people of their obligations**

9. 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.
10. The licence holder must provide the Regulator, on the Regulator's written request, signed statements from persons covered by this licence that the licence holder has informed those people of the conditions of this licence that apply to them.

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\* Attachments are included in the licence.

### **Licence holder to notify of circumstances that might affect suitability**

11. 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**

12. 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**

13. It is a condition of a licence that the licence holder inform the Regulator if the licence holder:
- (a) becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence;  
or
  - (b) becomes aware of any contraventions of the licence by a person covered by the licence; or
  - (c) becomes aware of any unintended effects of the dealings authorised by the licence.

14. 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**

15. If a person is authorised by this licence to deal with 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.

### **Remaining an accredited organisation**

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

## **SECTION 3 SPECIFIC CONDITIONS**

### **Locations and size of trial**

1. The permitted dealings with the GMOs may only be undertaken during the winter wheat growing seasons between April 2005 and January 2006 although disposal of the GMOs for purposes of the dealings may take place after January 2006.
2. The GMOs may only be grown at a single Location in the Corrigin Shire of Western Australia at GPS coordinates advised to the Regulator.
3. Reference Cereals may be grown at the Location while the GMOs are growing.
4. Reference Cereals must be handled and controlled as if they are the GMO.

*Note: The above condition has the effect that all ensuing conditions which apply to the GMO will also apply to Reference Cereals.*

5. The maximum permitted size of the Location is 0.45 hectares.
6. The licence holder must be able to access and control the Location where the GMOs are grown to the extent necessary to comply with this licence, for the duration of the life of the licence.
7. No GMOs may be planted at the Location after 31 July 2005.

### **Notice of planting**

8. The licence holder must provide a notice in writing to the Regulator each time the GMOs are planted at the Location. The notice must set out:
  - (a) the cultivars and lines of the GMOs that have been planted;
  - (b) the date on which planting of the GMOs commenced;
  - (c) details of the Location where the GMOs are planted, including GPS coordinates for the Location;
  - (d) the period during which the licence holder considers the GMOs are likely to flower; and
  - (e) the period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed in lieu of harvest).

*Note: Information contained in notices given to the Regulator pursuant to this condition can be viewed in the Site details that accompany this licence.*

9. The notice must be provided to the Regulator within 14 days of the date on which planting of the GMOs commenced.

### **Conditions relating to the Location**

10. The Location must be surrounded by:
  - (a) a fence at least 1.8 metres high with lockable gates that will exclude rabbits and large animals including macropods; and
  - (b) an Isolation Zone which includes the Monitoring Zone.
11. The outer edge of the Location must not be within 50 metres of a Natural Waterway.

12. Access to the Location must be restricted to persons covered by this licence.
13. Appropriate control measures must be implemented to minimise rodent numbers at the Location. These must include, but are not limited to, mowing the Monitoring Zone and keeping the Monitoring Zone free of weeds and other material capable of attracting and/or harbouring rodents while the GMOs are being grown at the Location.
14. 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.
15. The Location must be covered by a bird-proof net from 'milky dough' stage of the GMO until the GMO is harvested.

### **Conditions about the Isolation Zone**

16. No *Triticum* population may be grown in the Isolation Zone while the GMOs are being grown at the Location within it.
17. If any *Triticum* population occurs in the Isolation Zone while the GMOs are being grown at the Location within it, either the *Triticum* population or the GMOs in the Location must be destroyed prior to flowering of the GMO. If GMOs are destroyed pursuant to this condition, they are taken to have been harvested for the purposes of this licence and conditions relevant to harvested GMOs apply.
18. An Isolation Zone must be able to be accessed and controlled by the licence holder to an extent that is commensurate with the licence holder's rights to access and control the Location within it.

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

19. Fourteen days before the expected commencement of flowering of the GMOs at a Location, as notified to the Regulator pursuant to this licence, the Location must be inspected for the presence of Related Species that are not GMOs which must be destroyed before flowering.
20. Inspections must be conducted at least once every 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**

21. Fourteen days before the expected commencement of flowering of the GMOs at a Location, as notified to the Regulator pursuant to this licence, the Monitoring Zone must be inspected for the presence of Related Species and GMOs which must be destroyed before flowering.
22. Inspections must be conducted at least once every 14 days thereafter until the GMOs at the Location have been harvested.

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

23. Fourteen days before the expected commencement of flowering of the GMOs at a Location, the Isolation Zone must be inspected for the presence of *Triticum* populations.

24. Inspections must be conducted at least once every 14 days thereafter until the GMOs at the Location have finished flowering.

*Note: Other conditions in this licence, above, in relation to Isolation Zones, require the Destruction of the Triticum populations or the Cleaning of the Location if a Triticum population is found in an Isolation Zone.*

### **Notice of Harvest**

25. The licence holder must not harvest the GMOs without providing the Regulator with at least 7 days and not more than 20 days notice of an intention to harvest at the Location. Any change of intention prior to the intended harvest date must be notified to the Regulator as soon as is reasonably and practically possible.

26. 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 7 days of commencement of harvesting of the GMOs at the Location.

*Note: There are 2 relevant notices with respect to a forecast of harvest. One is a long-term forecast provided under conditions 8-9 and the other is a short term forecast under condition 25.*

### **GMOs must be either harvested or Destroyed**

27. Within 9 months of being planted, the GMOs must be either harvested or Destroyed.

28. If the GMOs are harvested, they must be harvested and stored separately from any other bread wheat (*Triticum aestivum* L.), durum wheat (*Triticum turgidum*), rye (*Secale cereale*), barley (*Hordeum vulgare*) or triticale and must be harvested either by hand or with a mechanical harvester.

29. If a mechanical harvester is used, the mechanical harvester must be fitted with a dust extractor and modified so as to capture Plant Material.

### **Seed and other Plant Material may be collected and stored**

30. Parts of GMOs (including leaf tissue, flower buds, seed, roots and stems) may be collected from the GMOs at the Location for the purpose of conducting experiments.

31. Parts of GMOs (including leaf tissue, flower buds, seed, roots and stems) that are collected may only be transported off the Location to:

(a) storage within a secure enclosed area that is signed so as to indicate GM Plant Material is stored within that area. GMOs must be stored in a sealed primary container capable of preventing dispersal of the GMO and/or Plant Material and which is enclosed by a locked outer container that is signed so as to indicate that it contains GM Wheat; or

(b) a facility certified by the Regulator to physical containment level 2 (PC2).

32. After any experiments with the GMOs or Parts of GMOs (including leaf tissue, flower buds, roots and stems) are completed, the GMOs, or Parts of GMOs, must be Destroyed.

### **Conditions in relation to the Cleaning of Location after GMOs are grown**

33. After the GMOs are harvested or Destroyed at the Location, the Location must be Cleaned.

34. The Location must be Cleaned within 14 days of harvest or Destruction of the GMOs in it, whichever occurs first.

### **Notice of Cleaning**

35. The licence holder must provide a notice in writing to the Regulator when a Location is Cleaned pursuant to this licence.

36. The notice must be provided to the Regulator within 14 days of the date on which Cleaning the Location concluded.

### **General conditions in relation to the Cleaning of all other places and Equipment used in connection with this licence**

37. If,

(a) an area or place other than the Location is used in connection with this licence, or

(b) Equipment is used in connection with the GMOs or Plant Material,

then that area, place or Equipment must also be Cleaned.

38. Cleaning must occur immediately or as soon as practicable after the use and before it is used for any other purpose.

39. If Equipment is Cleaned, the area in which the Equipment is Cleaned must also be Cleaned immediately or within 14 days of Cleaning of Equipment. (It is not necessary for Equipment to be Cleaned only at a Location).

40. On the request of the Regulator, the Regulator must, within 14 days of the request, be provided with written documentation of the procedures in place to ensure continuing compliance with these Cleaning conditions.

### **General conditions that apply wherever inspections must be undertaken for the existence of Volunteer plants and Related Species**

41. After harvest or destruction, the Location must be irrigated 3 times at intervals of at least 28 days so as to promote the growth of Volunteers.

42. After a Location is Cleaned, the following places must be inspected for the existence of Volunteer plants and Related Species:

(a) the Location;

(b) the Monitoring Zone; and

(c) any areas used to Clean Equipment.

43. Inspection must be performed by a person who is able to recognise Volunteer plants and Related Species.

44. The results of inspection activities must be recorded in a logbook. The logbook must be available on request for examination or photocopying by the OGTR. The findings of the inspections as recorded in the logbook must be provided to the Regulator every month and included in the licence holder's Annual Report to the Regulator. The logbook must contain at least the following:

- (a) details of the areas inspected;
- (b) details of the date of inspection;
- (c) the names of the person or persons who undertook the inspection and details of the experience, training or qualification that enabled them to recognise Volunteer plants and Related Species;
- (d) the number of Volunteer plants and Related Species observed, if any;
- (e) details of the development stages reached by the Volunteer plants and Related Species, if any; and
- (f) details of methods used to Destroy Volunteer plants and Related Species, if any.

45. Any Volunteer plants and Related Species identified must be Destroyed prior to the plants flowering.

46. Unless this licence provides otherwise, places subject to condition 42 must be inspected at least once every 30 days until the Regulator has issued a Sign-off.

47. If,

- (a) inspections have been routinely completed in a place for a period of 2 years, and
- (b) inspection records for that place show that no Volunteer plants and Related Species have been observed in the most recent 6 month inspection period,

the licence holder may make written application to the Regulator that these inspection conditions no longer apply in respect of that place.

48. Inspection conditions do not apply in respect of a place if the Regulator has issued a Sign-off in respect of that place.

### **Restrictions during and after the GMOs are grown**

49. If the GMOs are grown at the Location, and Sign-off has not occurred, no Related Species may be grown at the Location.

50. After Cleaning of the site the licence holder may plant species that are approved by a notice in writing by the Regulator.

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

## **Transportation of the GMOs and Plant Material**

51. Subject to the conditions immediately below in respect of transportation, the GMOs and Plant Material must be transported in accordance with the OGTR Guidelines for the Transport of GMOs (June 2001) issued by the Regulator.

52. Every container used to transport the GMOs and Plant Material must be labelled:

- (a) to indicate that it contains GM wheat; and
- (b) with telephone contact numbers for the licence holder and instructions to contact the licence holder in the event that the container is broken or misdirected.

53. Harvested seed from the GMOs may only be transported to the extent necessary to store it, export it, Destroy it or relocate it to a facility certified by the Regulator to physical containment level 2 (PC2).

54. The licence holder must have in place accounting procedures to verify whether the same quantity of GMOs and Plant Material that is sent is delivered. Routes, methods and procedures used for transportation in accordance with this licence must be documented.

## **Contingency Plans**

55. Within 30 days of the date of the commencement 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.

56. 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 and Plant Material; and
- (c) inspect and Destroy any Volunteer plants and Related Species that may exist as a result of the event.

57. 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, and the Regulator notified immediately or as soon as is practicable.

## **Compliance Management Plan**

58. Prior to growing the GMOs, a written Compliance Management Plan must be provided to the Regulator. The Compliance Management Plan must describe in detail how the licence holder intends to ensure compliance with these conditions and document that compliance.

## **Reporting**

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

### **Testing methodology**

60. 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 (at Attachment B) in a recipient organism. The instrument must be provided within 30 days of planting the GMOs.

### **GMOs and Plant Material must not be consumed**

61. The licence holder must not allow the GMOs or any products from the GMOs to be used as food for humans or as stockfeed.

DIR No: 053/2004

**\*Full Title:** Field trial of genetically modified salt tolerant wheat (*Triticum aestivum* L.) on saline land

**Organisation Details:**

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South Perth WA 6151

or

Locked Bag 888

Como WA 6952

Phone No: 08 9368 8750

Fax No: 08 9368 8751

**Project Supervisor Details:**

Surname: *[Personal Information Redacted]*

First name: *[Personal Information Redacted]*

Title: *[Personal Information Redacted]*

Phone No: *[Personal Information Redacted]*

Email: *[Personal Information Redacted]*

Position: *[Personal Information Redacted]*

Organisation: Grain Biotech Australia Pty Ltd

Postal address: PO Box 44, Bull Creek. WA. 6149.

**IBC Details:**

IBC Name: Murdoch University IBC

\* Information that must be included in the Record of GM Products and GMOs Dealings.

**GMOs Description**

- \* **Parent Organism Common Name:** Wheat
- \* **Parent Organism Scientific Name:** *Triticum aestivum* L. em Thell.

**Modified Traits**

- \***Category:** salt tolerance, herbicide tolerance
- \***Description:** Wheat plants have been genetically modified to have improved salt tolerance through increased levels of the amino acid proline which acts as an osmoprotectant. This was achieved by over-expression of the ornithine aminotransferase (OAT) enzyme involved in proline biosynthesis. The *oat* gene, and the cyanamide hydratase (*cah*) gene which confers tolerance to the herbicide cyanamide, were introduced using the biolistic transformation technique.

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

- Ornithine aminotransferase (*oat* gene) from *Arabidopsis thaliana* (salt tolerance); and
- Cyanamide hydratase (*cah* gene) from *Myrothecium verrucaria* (selectable marker, cyanamide resistance).

**Details**

This licence covers genetically modified wheat plants of line 2490-1 (in cultivar Westonia) and line 2721-1 (in cultivar Carnamah) which each contain the following genetic modifications:

- Ornithine amino transferase (*oat*) from *Arabidopsis thaliana* together with the *Ubi* promoter, including a first intron, and the zein terminator from *Zea mays*; and
- Cyanamide hydratase (*cah*) from *Myrothecium verrucaria* together with the *Ubi* promoter, including a first intron, and the zein terminator from *Zea mays*.

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