



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 054/2004

Licence Holder: CSIRO

Title: Field trial of genetically modified wheat (*Triticum aestivum* L.) with altered grain starch.

Issued: 13 April 2005

Varied: 30 January 2007

Varied: 9 January 2009

Varied: 23 June 2009

Surrendered: 23 December 2011

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 in relation to herbicide usage and herbicide resistance management

Some of the GMOs referred to in this licence have been modified to be tolerant to a herbicide. The Australian Pesticide and Veterinary Medicines Authority (APVMA) has responsibility for setting registration conditions for the use of herbicides in Australia, including implementation of herbicide resistance management programs. The licence holder may be required to comply with conditions imposed by the APVMA.

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 'DIR 054/2004 Site details'. This document can be viewed by accessing the document directly at

[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir054-3/\\$FILE/dir054sitedetails2.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir054-3/$FILE/dir054sitedetails2.pdf) or clicking at this link.

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;

'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*, *Hordeum*, *Secale*

‘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 CSIRO.

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);

* Attachments are included in the licence.

- (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.

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 GMOs may only be planted and grown during the winter wheat growing seasons between May 2005 and January 2008.
2. The GMOs may only be grown at a single Location at the Ginninderra Research Station, ACT at the GPS coordinates advised to the Regulator.
3. The maximum permitted size of the Location is 0.25 hectares.
4. 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. No GMOs may be planted at the Location after 31 July 2006.

Notice of planting

5. 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. You can view this document by clicking on the following link: [\[link to document\]](#)

6. 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

7. 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 like kangaroo;
 - (b) an Isolation Zone which includes the Monitoring Zone.
8. The outer edge of the Location must not be within 50 metres of a Natural Waterway.

9. Access to the Location must be restricted to persons covered by this licence.
10. 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.
11. 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.

Conditions about the Isolation Zone

12. No *Triticum* population may be grown in the Isolation Zone while the GMOs are being grown at the Location within it.
13. 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.

Note: if a Location has to be Destroyed because the above mentioned Triticum populations are present in the Isolation Zone, the Location is taken to have been harvested. Cleaning of the Location must occur soon afterwards (see the conditions below about Cleaning Locations post harvest) and post harvest monitoring of the Location must be commenced.

14. 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

15. 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.
16. 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

17. 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 the GMOs which must be destroyed before flowering.
18. 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

19. 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* population.

20. 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 population or the Cleaning of the Location if a Triticum population is found in an Isolation Zone.

Notice of Harvest

21. The licence holder must not harvest the GMO 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.

22. 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 condition 5(d) and the other is a short term forecast under condition 6.

GMOs must be either harvested or Destroyed

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

24. If the GMOs are harvested, they must be harvested by hand and stored separately from any other wheat.

Seed and other Plant Material may be collected and stored

25. 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.

26. 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 locked facility on at the Ginninderra Experiment Station that is signed so as to indicate GM Plant Material is stored within the facility; or
- (b) A facility certified by the Regulator to physical containment level 2 (PC2).

27. Stored GMOs must be stored in a sealed container that is signed so as to indicate that it contains GM Wheat. The storage unit must be locked when not in use. If the GMO is stored outside a facility it must be stored in a double container that is sealed and locked.

28. If the GM wheat grain is milled, milling must take place in a PC2 certified laboratory at CSIRO Plant Industry, Black Mountain, ACT.

29. 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

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

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

Notice of Cleaning

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

33. 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

34. 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.

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

36. 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).

37. 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

38. 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.

39. 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;
- (c) irrigation channels and drains through which water flows to and from the Location; and
- (d) any areas used to Clean Equipment.

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

41. 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.

42. Any Volunteer plant and Related Species identified must be Destroyed prior to the plant flowering.

43. Unless this licence provides otherwise, a place must be inspected at least once every 30 days until the Regulator has issued a Sign-off.

44. 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.

45. 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

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

47. 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

48. 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.

49. 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.

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

51. 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

52. 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.

53. 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.

54. 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

55. 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

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

Testing methodology

57. 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.

Consumption of GMOs and Plant Material

58. The licence holder must not allow the GMOs or any products from the GMOs to be used as food for humans or animals other than in accordance with conditions 59 and 60.

59. Products derived from the GMOs may be fed to rats at the CSIRO Human Nutrition Small Animal Facility (Adelaide, SA) or to pigs at the Animal Production Sciences Piggery (Department of Primary Industries, Werribee, Victoria) or at CSIRO Livestock Industries – Werribee Animal Facility – Australian Animal Health Laboratory (Werribee, Victoria).

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

DIR No: 054/2004

***Full Title**

Field trial of genetically modified wheat (*Triticum aestivum* L.) with altered grain starch

Organisation Details

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

Phone No: 1300 363 400

Project Supervisor Details

Surname: *[Personal Information Redacted]*

First Name: *[Personal Information Redacted]*

Title: *[Personal Information Redacted].*

Phone No: *[Personal Information Redacted]*

Email: *[Personal Information Redacted]*

Position: *[Personal Information Redacted]*

Organisation: CSIRO

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

IBC Details

IBC Name: CSIRO Plant Industry

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

GMOs Description

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

Modified Traits

- ***Category:** Altered grain starch composition, antibiotic resistance.
- ***Description:** Wheat plants have been genetically modified by the insertion of either of two gene silencing constructs that silence the gene encoding ‘starch enzyme’ (SE) I and II in the endosperm of the wheat grain, altering the composition of starch in the wheat grain from a majority of amylopectin starch to a majority of amylose starch, and an antibiotic resistance gene.

***Gene silencing constructs/genes responsible for conferring the modified traits**

- genomic sequences derived from the ‘SE I’ gene of *Triticum aestivum* arranged in such a way as to induce gene silencing in the endosperm of the wheat grain (gene silencing: altered starch composition).
- genomic sequences derived from the ‘SE II’ gene of *Triticum aestivum* arranged in such a way as to induce gene silencing in the endosperm of the wheat grain (gene silencing: altered starch composition).
- *nptII* gene from *Escherichia coli* (antibiotic resistance: selectable marker).

Details

The GMOs covered by this licence are as follows:

{Confidential Commercial Information}

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