



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 052/2004

Licence Holder: CSIRO

Title: Field trial of genetically modified rice (*Oryza sativa* L) – functional characterisation of the rice genome.

Issued: 18 February 2005

Varied: 20 June 2005

Varied: 30 September 2005

Surrendered: 31 July 2009

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 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 any part of the GMOs 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 have been planted pursuant to this licence

Information about where the GMOs have been planted pursuant to this licence can be found here [DIR 052 Site details](#).

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;

‘Bay’ means an area of land set aside for the purpose of growing the GMOs within Location One.

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

- (a) in relation to a Location or other area, the Destruction to the reasonable satisfaction of the Regulator, of the GMOs, Plant Material and any non-GM Rice plants planted and grown subject to this licence; or

- (b) in relation to Equipment, the removal from the Equipment and Destruction to the reasonable satisfaction of the Regulator, of the GMOs, Plant Material and any non-GM Rice plants planted and grown subject to this licence.

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

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

Note: ‘As the case requires’ has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, in the case of 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 150 metres in all directions from the outer edge of Location One;

‘Location’ means *both* Location One and Location Two;

*Note: This means that when a condition refers to a ‘Location’ rather than Location One or Location Two, the condition applies to **both** Location One and Location Two.*

‘Location One’ means an area of land containing three bays where the GMOs are planted and grown;

‘Location Two’ means an area of land adjacent to Location One where the progeny of the gene flow experiments will be grown;

‘Natural Waterways’ means waterways such as rivers, streams and creeks;

‘OGTR’ means the Office of the Gene Technology Regulator;

‘Plant Material’ means parts of GMOs and of any non-GM Rice plants planted and grown subject to this licence, including seed, stubble, leaves, roots and pollen, whether from the plant itself or derived from or produced by the plant;

‘Regulator’ means the Gene Technology Regulator;

‘Rice’ means plants of the *Oryza* genera;

‘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;

‘Volunteer plants’ means progeny of the GMOs or of any non-GM Rice plants planted and grown subject to this licence, and includes regrowth of GM or non-GM Rice plants.

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 and grow the GMOs, 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.

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 requested 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, other than disposal of the GMOs, may only be undertaken during the summer rice growing seasons in 2005/2006 and 2006/2007 and 2007/2008.
2. The GMOs must only be grown within Charles Sturt University campus in accordance with the restrictions set out in Attachment C. Attachment C sets out, for each growing season,
 - (a) when the permitted dealings may be undertaken;
 - (b) the Locations where the GMOs may be grown;
 - (c) the maximum number of Locations; and
 - (d) the maximum combined area of all Locations.
3. The licence holder must be able to access and control a Location where the GMOs are grown and the Isolation Zone to the extent necessary to comply with this licence, for the duration of the life of the licence.

Notice of planting

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

7. In Location One the GMOs must only be grown in a Bay which is lined with a layer of water impermeable material 60 cm below the soil surface and which is surrounded by earth banks at least 40 cm high and 100 cm wide.
8. Location One and Location Two must be located at least 1 kilometre from the nearest Natural Waterway.
9. Location One and Location Two must be within a chain link fence at least 2 metres high with lockable gates.
10. Location One must be covered by a cage capable of excluding birds and rodents. The design and specifications of this cage must be supplied to the Regulator before planting of GMOs occurs.
11. Location Two must be covered by nylon mesh that is in contact with the ground around the entire perimeter of the site.
12. Access to Location One and Location Two must be restricted to persons covered by this licence.
13. Location One must be surrounded by an Isolation Zone.
14. Subject to the immediately following condition, no Rice of any kind may be grown in the Isolation Zone.

15. Non-GM Rice may be planted and grown in the Isolation Zone but only within the fenced area surrounding Location One and Location Two and only for purposes of gene flow experiments.
16. If any Rice plant other than that grown pursuant to the immediately preceding condition is found to be present anywhere in the Isolation Zone then either the Rice plant or the GMOs in the Locations must be Destroyed prior to flowering.
17. Location Two must be surrounded by an earth bank 40 cm high and 100 cm wide.
18. Once planted, any non-GM Rice plants must be handled and controlled as if they are GMOs (i.e. any non-GM Rice plants within the fenced area are GMOs for the purposes of this licence and subject to other applicable conditions elsewhere in this licence).

Conditions that apply within the Isolation Zone while a GMO is planted at a Location

19. While GMOs are planted at a Location the licence holder must:
 - (a) use herbicide and/or mowing to control weeds in the area within the fence that surrounds the Locations;
 - (b) inspect the fence and netting or cage enclosing the Locations weekly and repair any damage immediately;
 - (c) inspect the fence-line surrounding the Locations weekly for the presence of weeds, and Destroy these, if any;
 - (d) inspect the area within the fence surrounding the Locations weekly for the presence of other material capable of harbouring rodents, and remove any such material;
 - (e) implement whatever additional measures are reasonably necessary to monitor for and control rodents as appropriate. These may include, but are not limited to trapping and baiting; and
 - (f) conduct monthly inspections of the Isolation Zone for the presence of any Rice not permitted to be grown by this licence and destroy any such Rice before flowering.
20. The activities conducted in order to satisfy the conditions that apply within the Isolation Zone, the dates and methods used, and the results of the inspection activities, must be recorded in a logbook. The information recorded in the log book must be provided to the Regulator once every 3 months, and must be included in the licence holder's Annual Report to the Regulator. The logbook must also be made available on request for examination or photocopying by the OGTR.

Destruction of GMOs and Plant Materials

21. Within 9 months of being planted, the GMOs and non-GM Rice planted in Location One must be harvested or Destroyed.

22. Within 2 months of being planted the Rice planted in Location Two must be harvested or Destroyed.
23. Any harvested GMOs or Plant Material not required for research purposes must be Destroyed.

Conditions in relation to the Cleaning of Locations after each crop of GMOs is grown

24. After the GMOs are harvested or Destroyed at a Location, the Location must be Cleaned.
25. A Location must be Cleaned within 14 days of harvest or Destruction of the GMOs in it, whichever occurs first.
26. The licence holder must provide a notice in writing to the Regulator when a Location is Cleaned pursuant to this licence. The notice must be provided to the Regulator within 14 days of the date on which Cleaning the Location concluded.

Conditions in relation to the Cleaning of all other places and Equipment used in connection with this licence

27. If:
 - (a) an area or place other than a 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.
28. Cleaning must occur immediately or as soon as practicable after the use and before it is used for any other purpose.
29. If Equipment is Cleaned, the area in which the Equipment is Cleaned must also be Cleaned. (It is not necessary for Equipment to be Cleaned only at a Location.)
30. On the request of the Regulator, the Regulator must be provided with written documentation of the procedures in place to ensure continuing compliance with these Cleaning conditions.

Conditions that apply in relation to inspection after a Location is Cleaned

31. After the Cleaning of Location One following the seasons 2005/2006 and 2006/2007, and before the next planting of the GMOs, the Location must be watered at least twice to induce germination and growth of volunteers.
32. After the Cleaning of Location One for the season 2007/2008 the Location must be watered at least twice during each ensuing October to February period until Sign-off.

33. For each of the two preceding conditions, an interval of at least 4 weeks must be allowed between each watering of the Location. Inspection for Volunteers must take place at least once during this interval.
34. After a Location is Cleaned, the following places must be inspected for the existence of Volunteer plants:
 - (a) the Location;
 - (b) the Isolation Zone;
 - (c) any areas used to Clean Equipment.
35. After a Location is Cleaned, all places subject to the immediately preceding condition must be inspected at least once every month during the months October to March and at least once every 3 months during the months April to September, until either:
 - (a) the GMOs are once again planted at the Location pursuant to this licence; or
 - (b) the Regulator has issued a Sign-off in respect of that place.
36. Inspection must be performed by a person who is able to recognise Volunteer plants.
37. 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 once every 3 months and included in the licence holder's Annual Report to the Regulator. The logbook must contain at least the following:
 - (a) Information on areas where Rice is likely to germinate and persist within the Isolation Zone.
 - (b) details of the areas inspected;
 - (c) details of the dates of inspections;
 - (d) 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;
 - (e) the number of Volunteer plants observed, if any;
 - (f) details of the development stages reached by the Volunteer plants, if any; and
 - (g) details of methods used to Destroy Volunteer plants, if any.
38. Any Volunteer plant identified must be Destroyed prior to the plant flowering.
39. If:

- (a) inspections have been routinely completed in a place for a period of a year; and
- (b) inspection records for that place show that no Volunteers 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.

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

Transportation of the GMOs and Plant Material

41. 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.
42. Every container used to transport the GMOs and Plant Material must be labelled:
- (a) to indicate that it contains GM Rice; 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.
43. GMOs and Plant Material may only be transported to the extent necessary to Destroy it or relocate it to a facility certified by the Regulator to physical containment level 2 (PC2).
44. 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

45. 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.
46. 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 for and Destroy any Volunteer plants that may exist as a result of the event.

47. 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.

Compliance Management Plan

48. 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.

Research

49. The licence holder must in consultation with the OGTR develop a research program to collect data on the occurrence of the gene flow from the GMOs to non-genetically modified Rice plants under Australian field conditions.

Reporting

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

Testing methodology

51. The licence holder must provide a written instrument to the Monitoring and Compliance Section of the OGTR 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

52. The GMOs or products derived from these plants must not be consumed by humans or used as stockfeed.

DIR No: 052/2004

***Full Title**

Field trial of genetically modified rice (*Oryza sativa* L.) - functional characterisation of the rice genome

Organisation Details

Postal Address: PO Box 1700
CANBERRA ACT 2600

Phone No: 02 6246 4450

Fax No: 02 6246 4455

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: PO Box 1700
CANBERRA ACT 2600

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: Rice

Scientific Name: *Oryza sativa* L.

*Modified traits:

Category: Expression of herbicide tolerance gene, antibiotic resistance genes and reporter genes

Description: Rice plants have been genetically modified, using the *Agrobacterium*-mediated transformation and *Ac/Ds* transposon techniques, to express various combinations of proteins conferring tolerance to the herbicide phosphinothricin or resistance to the antibiotics neomycin, kanamycin or hygromycin B and to express the GUS, GFP and/or EYFP reporter proteins.

*Genes responsible for conferring the modified traits:

bar gene from *Streptomyces hygroscopicus*;
nptII gene from *Escherichia coli*;
hph gene from *Escherichia coli*;
uidA gene from *Escherichia coli*;
gfp gene from *Aequorea victoria*;
eyfp gene modified from *gfp* gene above;

Details:

The GMOs covered by this licence are as follows:

(1) Rice plants modified by insertion of genetic material from any one of the following gene constructs referred to in application DIR 052/2004:

(a) pSK100 and pSK200, each of which contain:

➤ in the T-DNA element:

(i) the *gfp* gene together with the *Ubi1* promoter and the *nos* terminator;

(ii) the *hph* gene together with the *35S* promoter and the *nos* terminator;

➤ in the *Ds* element:

(iii) the *uidA* gene together with the transcriptional activator or splice acceptor and with the *nos* terminator;

(iv) the *bla* gene and ColE1 origin of replication; and

(v) the *nptII* gene together with the *mas 2'* promoter and the *nos* terminator.

- (b) pMNRTT223nb, pMNRTT224na and pMNRTT244nb, each of which contain:
- in the T-DNA element:
 - (i) the *bar* gene together with the *35S* promoter and the *ocs* terminator;
 - (ii) the *hph* gene together with the *35S* promoter and the *nos* terminator;
 - in the *Ds* element:
 - (iii) the *uidA* gene together with the transcriptional activator or splice acceptor and with the *nos* terminator;
 - (iv) the *bla* gene and ColE1 origin of replication; and
 - (v) the *nptII* gene together with the *mas 2'* promoter and the *nos* terminator.
- (c) pMN393a and pMN393b, each of which contain:
- in the T-DNA element:
 - (i) the *hph* gene together with the *35S* promoter, the 4th intron of the *Arabidopsis thaliana* G-protein gene and the *tml* terminator;
 - in the *Ds* element:
 - (ii) the *uidA* gene together with the splice acceptor sequences and the *nos* terminator;
 - (iii) the *bla* gene and ColE1 origin of replication;
 - (iv) the *bar* gene together with the *35S* promoter and the *ocs* terminator; and
 - (v) the *eyfp* gene together with the splice acceptor sequences and the *nos* terminator.
- (d) pEUTT334BN, which contains:
- in the *Ds* element:
 - (i) the *gfp* gene together with the splice acceptor sequences and the *nos* terminator;
 - (ii) the *bla* gene and ColE1 origin of replication;
 - (iii) the *hph* gene together with the *35S* promoter, the 4th intron of the *Arabidopsis thaliana* G-protein gene and the *tml* terminator; and
 - (iv) the *uidA* gene together with the splice acceptor sequences and the *nos* terminator.

(2) Progeny of the GMOs described at (1) above that are the result of those plants self-pollinating.

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

Attachment C

Season	Location where GMOs may be grown	Maximum area Location
Summer 2005/6	Location One	0.05 ha
Summer 2006/7	Location One	0.05 ha
	Location Two	0.1 ha
Summer 2007/8	Location One	0.05 ha