



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

Licence for dealings involving the intentional release of GMOs into the environment

Licence No: DIR 049/2004

Licence Holder: CSIRO

Title: GM cotton field trial – evaluation under field conditions of the cotton rubisco small subunit promoter driving a reporter gene.

Issued: 21 October 2004

Varied: 4 March 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 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 parts of the GM cottons such as oil and linters derived from GM cottonseed could be used as human food. This licence contains a condition that prohibits this use.

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: [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;

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

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

‘Cotton’ means plants of the species *Gossypium hirsutum* L. and *G. barbadense* other than the GMOs and Pollen Trap plants;

‘cotton’ means plants of the species *Gossypium hirsutum* L. and *G. barbadense*;

‘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) 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;

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

‘Plant Material’ means viable parts of GMOs and Pollen Trap plants, including seed, stubble, pollen, whether from the plant itself or derived from or produced by the plant;

‘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;

‘Pollen Trap’ means an area of land, extending at least 20 metres in all directions from the outside edge of a Location;

‘Pollen Trap plant’ means cotton from a Pollen Trap planted in compliance with special condition 10 of this licence;

‘Regulator’ means the Gene Technology Regulator;

‘Seed’ means whole cotton seed from the GMOs or Pollen Trap plants, including seed cotton, fuzzy seed and black seed;

‘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 Pollen Trap plants, or regrowth of previous GM or non-GM cotton 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, 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. The permitted dealings may only be undertaken for the purpose described at Attachment B.

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.

Additional information to be given to the Regulator

12. 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.

People dealing with GMOs must allow auditing and monitoring of the dealing

13. 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

14. 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 cotton growing seasons in 2004/2005 and 2005/2006 between October 2004 and May 2006.
2. The GMOs must only be grown in accordance with the restrictions set out in Attachment C. Attachment C sets out, for each growing season, when the permitted dealings may be undertaken:
 - (a) the Location where the GMOs may be grown;
 - (b) the maximum number of Locations; and
 - (c) 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 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.

Note : Information about where the GMOs have been planted pursuant to this licence can be found here: [Site Details](#)

Notice of Cleaning

7. The licence holder must provide a notice in writing to the Regulator when a Location is Cleaned pursuant to this licence.
8. The notice must be provided to the Regulator within 14 days of the date on which Cleaning the Location concluded.

Pollen Traps

9. A Pollen Trap must surround every Location.
10. A Pollen Trap must contain non-genetically modified plants of the species *Gossypium hirsutum* L. that is grown in such a way as to reasonably promote a dense and vigorous growth and flowering of the non-genetically modified *Gossypium hirsutum* L. at the same time as the GMOs. Pollen Trap plants must be grown in the Pollen Trap while ever the GMOs are being grown at the Location within it.
11. The edge of the Pollen Trap that is farthest from the GMOs (the outer edge of the Pollen Trap) must not be within 50 metres of a Natural Waterway.
12. Once planted, Pollen Trap plants and Plant Material must be handled and controlled as if they are GMOs (ie. Pollen Trap plants and Plant Material are GMOs for the purposes of this licence and subject to other applicable conditions elsewhere in this licence).
13. A Pollen Trap 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.

Seed and other Plant Material may be collected

14. Parts of GMOs (including leaf tissue, flower buds, roots and stems) may be collected from a Location for the purpose of conducting experiments on it.
15. Parts of GMOs (including leaf tissue, flower buds, roots and stems) that are collected may only be transported off the Location to:
 - (a) a locked facility on the same property as the Location 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).
16. Parts of GMOs (including leaf tissue, flower buds, roots and stems) that are collected from the Location may be stored in a locked facility on the same property as the Location that is signed so as to indicate GM Plant Material is stored within the facility. Parts of GMOs stored in the facility must be stored in a sealed container.

17. 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.

Crops of the GMOs must be either harvested or Destroyed

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

19. If the GMOs are harvested, they must be harvested separately from any other Cotton.

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

20. After the GMOs are harvested or Destroyed at a Location, the Location and the Pollen Trap around it must be Cleaned.

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

22. A Pollen Trap must be Cleaned within 14 days of the Cleaning of the Location within it.

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

23. If:

(a) an area or place other than a Location or Pollen Trap is used in connection with this licence; or

(b) Equipment is used in connection with the GMOs, Pollen Trap plants or Plant Material;

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

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

25. 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.)

26. 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.

General conditions that apply wherever inspections must be undertaken for the existence of Volunteer plants

27. After a Location is Cleaned, the following places must be inspected for the existence of Volunteer plants:
- (a) the Location;
 - (b) the Pollen Trap;
 - (c) irrigation channels and drains through which water flows to and from the Location and the Pollen Trap;
 - (d) any areas used to Clean Equipment.
28. Inspection must be performed by a person who is able to recognise Volunteer plants.
29. 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 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;
 - (d) the number of Volunteer plants observed, if any;
 - (e) details of the development stages reached by the Volunteer plants, if any; and
 - (f) details of methods used to Destroy Volunteer plants, if any.
30. Any Volunteer plant identified must be Destroyed prior to the plant flowering.
31. Unless this licence provides otherwise, a place must be inspected at least once every 60 days until the Regulator has issued a Sign-off.
32. 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.

33. 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

34. Subject to condition 37 below, if the GMOs are grown at a Location, no Cotton may be grown in the Location or its Pollen Trap and that Location cannot be used in the following growing season to grow the GMOs.
35. Subject to conditions 36 and 37 below, if the GMOs are grown at a Location, no other plants may be planted at the Location and only Pollen Trap plants may be planted in the Pollen Trap.
36. Subject to condition 37 below, after the GMOs have been grown at a Location, only the following plants may be grown at the Location and its Pollen Trap:
- (a) grasses (grass pastures);
 - (b) cereals (cereal crops);
 - (c) plants agreed to in writing by the Regulator.
37. Conditions 34, 35 and 36 above, do not apply in respect of a place if the licence holder has received a Sign-off in respect of that place.

Transportation of the GMOs, Pollen Trap plants and Plant Material

38. Subject to the conditions immediately below in respect of transportation, the GMOs, Pollen Trap plants and Plant Material must be transported in accordance with the OGTR Guidelines for the Transport of GMOs (June 2001) issued by the Regulator.
39. Every container used to transport the GMOs, Pollen Trap plants and Plant Material must be labelled:
- (a) to indicate that it contains GM cotton; 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.
40. Harvested seed from the GMOs or Pollen Trap plants may only be transported to the extent necessary to store it, export it, Destroy it by burning it or relocate it to a facility certified by the Regulator to physical containment level 2 (PC2).
41. The licence holder must have in place accounting procedures to verify whether the same quantity of GMOs, Pollen Trap plants 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

42. 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, Pollen Trap plants or Plant Material, outside an area that must be inspected.
43. 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, Pollen Trap plants and Plant Material; and
 - (c) inspect and Destroy any Volunteer plants that may exist as a result of the event.
44. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs, Pollen Trap plants or Plant Material is discovered outside an area that must be inspected.

Compliance Management Plan

45. 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

46. The licence holder must provide the Regulator with a written report within 90 days of each anniversary of this licence, in accordance with any Guidelines issued by the Regulator in relation to annual reporting. This report must include information on any adverse impacts on human health and safety or the environment, caused as a result of the GMOs, Pollen Trap plants or Plant Material.

Testing methodology

47. 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, Pollen Trap plants and Plant Material must not be consumed

48. The licence holder must ensure that the GMOs, Pollen Trap plants and products derived from these plants are not consumed by humans or used as stockfeed.

DIR No: 049/2004

***Full Title**

GM cotton field trial – evaluation under field conditions of the cotton rubisco small subunit promoter driving a reporter gene.

Organisation Details

Postal address: CSIRO
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Project Supervisor Details

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Position: *[Personal Information Redacted]*

Organisation: CSIRO Plant Industry

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IBC Details

IBC Name: CSIRO Plant Industry

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

GMOs Description

*Parent Organism

Common name: Cotton

Scientific Name: *Gossypium hirsutum* L.

*Modified Trait(s)

Category: Reporter gene expression and antibiotic resistance

Description: Cotton plants have been genetically modified, using the *Agrobacterium* mediated transformation technique, to express the GUS reporter protein and to be resistant the antibiotic kanamycin or both kanamycin and the antibiotic hygromycin B.

*Genes responsible for conferring the modified trait(s)

β -glucuronidase (*uidA*) gene from *Escherichia coli* (GUS reporter protein);

Neomycin phosphotransferase type II (*nptII*) gene from *Escherichia coli* (antibiotic resistance, selectable marker);

Hygromycin phosphotransferase (*hph*) gene from *Escherichia coli* (antibiotic resistance, selectable marker).

Details

The GMOs covered by this licence are as follows:

- (1) Cotton plants containing one or more copies of the following genetic modification:
 - (a) the *nptII* gene from *Escherichia coli* together with the *nos* promoter and terminator from *Agrobacterium tumefaciens*; and
 - (b) the *uidA* gene from *Escherichia coli* (itself containing a small intron from the *Ricinus communis* catalase gene), together with the 35S promoter from Cauliflower mosaic virus and the *ocs* terminator from *Agrobacterium tumefaciens*;
- (2) Cotton plants containing one or more copies of the following genetic modification:

- (a) the *nptII* gene from *Escherichia coli* together with the *nos* promoter and terminator from *Agrobacterium tumefaciens*;
 - (b) the *hph* gene from *Escherichia coli*, together with the 35S promoter from Cauliflower mosaic virus and *nos* terminator from *Agrobacterium tumefaciens*; and
 - (c) the *uidA* gene from *Escherichia coli* (itself containing a small intron from the *Ricinus communis* catalase gene), together with the *rbcS* promoter from cotton and the *nos* terminator from *Agrobacterium tumefaciens*;
- (3) Progeny of the GMOs described at (1) and (2) above that are the result of those plants self-pollinating.

Purpose of the permitted dealings

The purpose of the permitted dealings with the GMOs is to evaluate the performance of the 35S and *rbcS* promoters in controlling expression of the reporter gene under field conditions and to collect tissue samples and seed.

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

Attachment C

Season	Location where GMOs may be grown	Maximum No of Locations per season	Maximum combined area of all Locations per season
Summer 2004/5	Australian Cotton Research Institute, Narrabri, NSW	1	0.1 ha
Summer 2005/6	Australian Cotton Research Institute, Narrabri, NSW	1	0.1 ha