

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

Field evaluation of genetically modified high oleic cotton with modified fatty acid desaturase and antibiotic resistance genes

Licence No. 039/2003

Issued 28 October 2003

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Licence Holder: CSIRO



Office of the
Gene Technology Regulator

Gene Technology Regulation in Australia

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form a substantial part of a 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 to the environment in assessing applications for dealings involving the intentional release of GMOs into the Australian environment.

Other agencies that also regulate GMOs or GM products include FSANZ, APVMA, TGA, NICNAS, NHMRC and AQIS. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

SECTION 1 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 GMO 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 the GMOs grown in the Location pursuant to this Licence.

Informing people of their obligations

9. The licence holder must inform each 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. The licence holder must inform the Regulator in writing 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 2 INTERPRETATIONS 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:

Words and phrases used in this licence have the same meanings as they do in the Act and the Regulations;

Words importing a gender include any other gender;

Words in the singular include the plural and words in the plural include the singular;

Words importing persons include a partnership and a body whether corporate or otherwise;

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;

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning;

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, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants 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, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants from the Equipment, to the reasonable satisfaction of the Regulator.

'Cotton' means plants of the species *Gossypium hirsutum* L.

'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) root cutting; or
- (d) burning; or

- (e) treatment with herbicide; 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 (eg bags, containers, trucks), clothing and tools.

'GM' means genetically modified.

'GMOs' means genetically modified organism or organisms authorised for release by this licence.

'Location' means an area of land where the GMOs are planted and grown.

'Material from Pollen Trap plants' means seed, stubble, pollen or any material (including parts of a plant) that is derived from or produced by cotton from a Pollen Trap.

'Material from the GMOs' means material (including part of a plant) that is derived from or produced by the GMOs.

'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.

'Regulator' means the Gene Technology Regulator.

'Volunteer plants' means progeny of the GMOs or Pollen Trap plants, or regrowth of previous GM or non-GM cotton plants.

SECTION 3 SPECIFIC CONDITIONS

Locations and size of trial

1. The permitted dealings with the GMOs may be undertaken during the Cotton growing season Of 2003 – 2004 within the Shire of Narrabri, New South Wales.
2. The GMOs may only be grown at a single Location. That Location must not exceed 2 hectares.
3. At least 7 days prior to commencing to grow the GMOs at the Location, the Location's GPS coordinates and either a street address, or other directions to the Location, must be provided to the Regulator by notice in writing.
4. The licence holder must be able to access and control a Location to the extent necessary to comply with this licence, for the duration of the life of the licence.
5. Planting the GMOs at the Location must not commence after 31 May 2004.

Notification of planting of the GMOs

6. The licence holder must provide notices in writing to the Regulator of the actual date or dates of commencement of planting of the GMOs at the Location (and Pollen Trap in respect of the Location) ('the actual planting date notice'). This notice must be provided within 7 days of commencement of planting of the GMOs at the Location.

Notification of commencement of flowering of the GMO

7. The licence holder must provide notices in writing to the Regulator in respect of each of the following:
 - (a) the short term forecasted date or dates of commencement of flowering of the GMOs at the Location (and Pollen Trap in respect of each Location) ('the short term forecast flowering date notice'). This notice must be provided at least 7 days, and not more than 20 days, prior to the forecasted date or dates of commencement of flowering set out in the notice; and
 - (b) the actual date or dates of commencement of flowering of the GMOs at the Location (and Pollen Trap in respect of the Location) ('the actual flowering date notice'). This notice must be provided within 7 days of commencement of flowering of the GMOs at the Location.

Notification of commencement of seed set of GMO

8. The licence holder must provide notices in writing to the Regulator in respect of each of the following:
 - (a) the short term forecasted date or dates of commencement of seed set of the GMOs at the Location (and Pollen Trap in respect of the Location) ('the short term forecast seed set date notice'). This notice must be provided at least 7 days, and not more than 20 days, prior to the forecasted date or dates of commencement of seed set, as set out in the notice; and

- (b) the actual date or dates of commencement of seed set of the GMOs at the Location (and Pollen Trap in respect of the Location) ('the actual seed set date notice'). This notice must be provided within 7 days of commencement of seed set of the GMOs at the Location.

Notification of commencement of harvest of GMOs

- 9. The licence holder must provide notices in writing to the Regulator in respect of each of the following:
 - (a) the short term forecasted date or dates of commencement of harvesting of the GMOs at the Location (and Pollen Trap in respect of the Location) ('the short term forecast harvest date notice'). This notice must be provided at least 7 days, and not more than 20 days, prior to the forecasted date or dates of commencement of harvesting set out in the notice; and
 - (b) the actual date or dates of commencement of harvesting of the GMOs at the Location (and Pollen Trap in respect of the Location) ('the actual harvest date notice'). This notice must be provided within 7 days of commencement of harvesting of the GMOs at the Location.

Pollen Traps

- 10. A Pollen Trap must surround the Location.
- 11. The Pollen Trap must contain non-GM Cotton that is grown in such a way as to reasonably promote a dense and vigorous growth and flowering of the non-GM cotton at the same time as the GMOs.
- 12. 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.
- 13. Pollen Trap plants must be handled and controlled as if they are the GMOs (ie subject to other applicable conditions elsewhere in this licence), and Material from Pollen Trap plants must be handled and controlled as if it is Material from the GMOs (ie subject to other applicable conditions elsewhere in this licence).
- 14. 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.

Research requirement

- 15. The licence holder must, in consultation with the OGTR, conduct research on gene transfer from the GMOs to the Pollen Trap.
- 16. In accordance with any Guidelines issued by the Regulator in relation to annual reporting, the licence holder must provide the Regulator with a written report of the progress and results of the research. This report must accompany the annual report to be sent to the Regulator.

Harvest and post-harvest procedures

- 17. If the GMOs or Pollen Trap plants are harvested, they must be harvested separately from any other Cotton.

18. If seed cotton harvested from the GMOs or from Pollen Trap plants is ginned, it must be ginned separately from any other Cotton.
19. The GMOs, Material from the GMOs, Pollen Trap Plants and Material from Pollen Trap plants must not be used for stockfeed, except as authorised by this licence under paragraph 20, and must not enter the human food supply.
20. Stored GM cotton seed may be fed to ewes as part of a feeding trial. A maximum of 8 animals may be fed GM cotton seed. The trial must be conducted in an enclosed facility with a concrete floor. Cotton seeds passing through the animals must be collected for 5 days after feeding of GM seeds to the animals has ceased. Any GM seeds passing through the animals must be destroyed. Milk from the ewes fed GM seed must not be given to lambs. Meat products and any other food products from the ewes fed GM seed must not be consumed by humans or animals. Details of any feeding trial sites must be provided to the OGTR at least 7 days before the trial commences.
21. Following ginning, seed from the GMOs and Pollen Trap plants must be:
 - (a) stored in a sealed container, within a locked facility that is signed so as to indicate that GM cottonseed is stored within the facility; or
 - (b) Destroyed by burning or by processing for the extraction of oil.
22. Any GM seed obtained from ginning may only be transported to the extent necessary to store them, Destroy them by burning, by processing for the extraction of oil, by feeding to animals subject to this licence or to take them to a facility certified by the Regulator to physical containment level PC2.
23. Cotton lint obtained from ginning of seed cotton harvested from the GMOs or Pollen Trap plants may be sold.

Cleaning - post harvest and generally

24. Equipment, the Location or other area used pursuant to this licence in respect of GMOs, Material from GMOs, Pollen Trap plants or Material from Pollen Trap plants, must be Cleaned.
25. For the Location, either within 14 days of harvest of the GMOs or by 31 May 2004, whichever occurs first, the Location must be Cleaned.
26. If Equipment is Cleaned, the area in which the Equipment is Cleaned must also be Cleaned. (For the sake of clarity, it is not necessary for Equipment to be Cleaned only at the Location.)
27. Cleaning must occur immediately or as soon as practicable after the use and before it is used for any other purpose. (For example, if GM seed is ginned, the gin must be Cleaned immediately following its use and before any other Cotton is ginned).
28. On the request of the Regulator, the Regulator must be provided with written documentation of the procedures in place to ensure continuing compliance with the Cleaning conditions in this licence.

Inspection

29. Following Cleaning of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants at the Location or other area, the following places must be inspected for the existence of Volunteer plants:
 - (a) the Location;
 - (b) the Pollen Trap in respect of the Location;
 - (c) irrigation channels and drains through which water flows to and from the Location and the Pollen Trap; and
 - (d) any areas used to Clean Equipment used in connection with the GMOs or to Destroy the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants.
30. Inspection must be performed by a person who is able to recognise Volunteer plants.
31. All the places required to be inspected must be inspected at least once every 2 months for a period of at least 12 months that commences the last day of Cleaning of the Location.
32. 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 monitoring 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.
33. Any Volunteer plant identified must be Destroyed prior to the plant flowering.

General conditions on use of Locations post-harvest

34. If the GMOs are grown at the Location, no other cotton plant of any kind may be grown at the Location, or Pollen Trap in respect of the Location, after harvest of the GMOs or Pollen Trap plants until inspection obligations are completed.
35. If the GMOs are grown at the Location, no plants may be planted at the Location, or Pollen Trap in respect of the Location until inspection obligations are completed unless:
 - (a) the plants are grasses (grass pastures), cereals (cereal crop); or
 - (b) the plants are plants agreed to in writing by the Regulator; and
 - (c) the Regulator is satisfied that inspection and Destruction of Volunteer plants prior to flowering will not be adversely affected by the planting.

Transportation of the GMOs, Material from GMOs, Pollen Trap plants and Material from Pollen Trap plants

36. Subject to the conditions immediately below in respect of transportation, the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants must be transported in accordance with the OGTR Guidelines for the Transport of GMOs (June 2001) issued by the Regulator.
37. Harvested GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants may be transported to a ginning facility in a cotton module that is:
 - (a) completely enclosed within 2 layers of tarpaulin ('double wrapped in tarpaulin'); or
 - (b) completely enclosed within a layer of tarpaulin inside a layer of shade cloth ('double wrapped in tarpaulin and shade cloth');
 - (c) contained within an enclosed chain-bed truck specifically designed for the purpose of transporting cotton modules.

Explanatory note: double wrapping is intended to prevent dissemination of the enclosed material during transportation.

38. Cotton lint derived from GMOs and Pollen Trap plants from ginning is not subject to transportation conditions.
39. Every container used to transport the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants 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. The licence holder must have in place accounting procedures to verify whether the same quantity of GMOs, Material from the GMOs, Pollen Trap Plants or Material from Pollen Trap plants sent is delivered and must document routes, methods and procedures used for transportation of GMOs, Material from GMOs, Pollen Trap plants and Material from Pollen Trap plants.

Contingency Plans

41. 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, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants outside an area that must be inspected.
42. 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, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants; and
 - (c) inspect and Destroy any Volunteer plants that may exist as a result of the event.

43. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants is discovered outside an area that must be inspected.

Compliance Management Plan

44. 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

45. 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, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants.

Testing methodology

46. 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 12 months of the issuing of this licence.

Use of GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants

47. The licence holder must ensure that the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants are not consumed by humans or used in manufacture of animal feed or therapeutics.

ATTACHMENT A

DIR No: 039/2003

***Full Title:** Field evaluation of genetically modified high oleic cotton with modified fatty acid desaturase and antibiotic resistance genes

Organisation Details

Postal address: CSIRO
PO Box 1700
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Project Supervisor Details

Surname: *[Personal Information Redacted]*

First Name: *[Personal Information Redacted]*

Title: *[Personal Information Redacted]*

Phone No: *[Personal Information Redacted]*

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Email Address: *[Personal Information Redacted]*

Position: *[Personal Information Redacted]*

Organisation: CSIRO Plant Industry

Postal Address: GPO Box 1600
Canberra ACT 2601

IBC Details

IBC Name: CSIRO Plant Industry (Black Mountain)

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

ATTACHMENT B

GMOs Description

***Parent Organism(s) Common Name:** Cotton

***Parent Organism(s) Scientific Name:** *Gossypium hirsutum* L.

Modified Trait(s):

***Category:** High oleic cottonseed.

***Description:** Cotton plants have been genetically modified by introduction of an altered cotton gene that changes fatty acid ratios in cottonseed and a bacterial antibiotic resistance gene used as a selectable marker.

***Gene Responsible for Conferring the Modified Trait(s):**

The altered *ghFAD2-1* gene from *Gossypium hirsutum* confers high oleic acid content in cottonseed.

The *nptII* gene from *Escherichia coli* confers antibiotic resistance.

Purpose of the Dealing with the GMOs:

Evaluate the agronomic performance of genetically modified cotton and maintenance of the high oleic trait under Australian field conditions.

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