



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

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

Licence No.: DIR 058/2005

Licence holder: Deltapine Australia Pty Ltd

**Title: Limited and controlled release
of insect resistant (VIP) GM cotton**

Issued: 26 October 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

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 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:

- (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, 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.

‘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; or
- (f) 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 (eg bags, containers, trucks), clothing and tools.

'GM' means genetically modified.

'GMOs' means the genetically modified organisms listed in Attachment B and authorised for release by this licence.

'Location' means an area of land where the GMOs or other plants are planted and grown pursuant to this licence but does not include a Pollen Trap.

'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 the GMOs, Pollen Trap Plants or non-GM cotton grown at the Location including seed, stubble and pollen, whether from the plant itself or derived from or produced by the plant.

'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 non-GM Cotton or GM Bollgard II[®] Cotton from a Pollen Trap.

'Regulator' means the Gene Technology Regulator.

'Sign-off' means a notice in writing from the Regulator, in respect of a place or a Location, whichever applies, that post harvest inspection conditions no longer apply in respect of that place or Location.

'Volunteer Plants' means progeny of the GMOs, Pollen Trap Plants or non-GM cotton grown at the Location, 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 Deltapine Australia Pty Ltd.

Project Supervisor

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

No dealings with GMOs except as authorised by this licence

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

Persons covered by this GMO licence

6. 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

7. 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.
8. 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.

Applicant to notify of circumstances that might affect suitability

9. 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

10. 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

11. 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.
12. 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

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

GMOs covered by this licence

1. The GMOs covered by this licence are described at Attachment B.

Permitted dealings

2. 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.
3. Non-GM Cotton may be planted and grown at the Location, but if planted, must be handled and controlled as if it were a GMO for purposes of this licence.

Locations and size of trial

4. The permitted dealings with the GMOs may be undertaken during the cotton growing seasons in Summer 2005/2006 within the Shires of Narrabri, NSW and Emerald, QLD.
5. The maximum number of Locations for this release is two. The maximum combined area of both Locations is limited to 1 hectare,
6. The maximum size of any individual Location must not exceed 0.5 of a hectare.
7. 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.

Notice of intention to plant and of planting

8. The licence holder must provide a notice in writing to the Regulator which contains:
 - (a) the date on which planting of the GMOs is intended to commence;
 - (b) the date on which planting of any non-GMOs on a Location is intended to commence;
 - (c) details of the Location where the GMOs will be planted, including a street address and GPS coordinates for the Location;
 - (d) the period during which the licence holder considers the GMOs are likely to flower;
 - (e) the period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed in lieu of harvest); and
 - (f) if GMOs have previously been planted at a site, a history indicating how the site has been used in the preceding two years, including details of previous GMOs and post-harvest crops planted at the Location.
9. The notice must be provided to the Regulator at least 7 days prior to the date on which planting of the GMOs is intended to commence.

10. Notice of the actual date of planting must be provided to the Regulator if it differs from the forecasted/intended date of planting.

Note: Information about where the GMOs are being planted pursuant to this licence, including the exact site details, will be made available at the beginning of the summer 2005/2006.

Notice of harvest and Cleaning following harvest

11. The licence holder must provide the Regulator with a notice of intention to harvest GMOs at the Location. This notice must be provided at least 7 days, and not more than 21 days, in advance of the intended date of harvest set out in the notice. Any change of intention prior to the intended harvest date must be notified to the Regulator as soon as is reasonably and practically possible.
12. The licence holder must provide the actual date or dates of commencement of harvesting of 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 8 and the other is a short-term forecast under Condition 10.

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

Measures to manage Gene Flow

14. Each Location must be surrounded by a Pollen Trap.
15. Each Pollen Trap must contain only Pollen Trap Plants grown in such a way as to reasonably promote a dense and vigorous growth and in such a way as to ensure that the Pollen Trap Plants flower at the same time and for the same period of time as the GMOs.
16. The edge of every 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.
17. 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 Plant Material must be handled and controlled as if it is the GMOs (ie subject to other applicable conditions elsewhere in this licence).
18. 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.

Material from the GMOs may be collected

19. Any material from the GMOs, including Plant Material, may be collected from a Location for the purpose of conducting experiments on it.
20. Any material from the GMOs, including Plant Material, that is collected may be transported off the Location to:

- (a) a facility certified by the Regulator to physical containment level 2 (PC2); or
- (b) a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is stored within the facility,

and may be experimented on and stored in any one or more of these facilities.

- 21. After any experiments with the material from the GMOs are completed, the Plant Material must be Destroyed.

Note: the above conditions do not permit experiments involving any genetically modified organisms other than those covered by this licence to be performed in these facilities.

Harvest and post-harvest procedures

- 22. If the GMOs or Pollen Trap Plants are harvested, they must be harvested separately from any other crop.
- 23. If seed Cotton harvested from the GMOs or from Pollen Trap Plants is ginned, it must be ginned separately from any other crop.
- 24. 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 Cotton seed is stored within the facility;
 - (b) exported; or
 - (c) Destroyed by burning.
- 25. Any GM Cotton seed obtained from ginning may only be transported to the extent necessary to store them, export them, Destroy them by burning, or take them to a facility certified by the Regulator to physical containment level 2 (PC2).
- 26. Cotton lint obtained from ginning of seed Cotton harvested from the GMOs or Pollen Trap Plants may be sold.

Cleaning – post harvest and generally

- 27. Equipment, a Location or other area (including a gin) used pursuant to this licence in respect of GMOs, Pollen Trap Plants or Plant Material must be Cleaned.
- 28. For each Location, either within 14 days of harvest of the GMOs or within 9 months of planting of the GMOs, whichever occurs first, the Location must be Cleaned.
- 29. 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 a Location.)
- 30. Cleaning must occur immediately or as soon as practicable after 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 crop is ginned.)

31. 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

32. Following Cleaning of a 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;
 - (d) any areas used to Clean Equipment used in connection with the GMOs at the Location or to Destroy the GMOs, Pollen Trap Plants or Plant Material.
33. Inspection must be performed by a person who is able to recognise Volunteer Plants.
34. For each Location, all the places required to be inspected must be inspected at least once every 2 months, commencing on the last day of Cleaning of the Location and continuing until the Regulator has issued a Sign-off.
35. The results of inspection activities must be recorded in a logbook or paper file. The findings of the inspections as recorded in the logbook or paper file must be forwarded to the Regulator within 14 days of inspection taking place and must also be included in the licence holder's Annual Report to the Regulator. The logbook or paper file 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 means of inspection used;
 - (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.
36. Any Volunteer plant must be Destroyed prior to the plant flowering.
37. For each Location, and all places in respect of that particular Location as listed in condition 31,
 - (a) if inspections have been routinely completed in that Location and all those places for a period of at least 12 months, and,

- (b) if inspection records for that Location and all those places 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 to that particular Location and the places in respect of that particular Location as listed in condition 31.

- 38. These inspection conditions do not apply in respect of a place if the licence holder has received a Sign-off.

General conditions on use of Locations post-harvest

- 39. If the GMOs are grown at a Location, no plants may be planted at the Location, Pollen Trap in respect of the Location until inspection obligations are completed unless:
 - (a) the plants are grasses (grass pastures), cereals (cereal crops); or
 - (b) the plants are plants agreed to in writing by the Regulator.

Transportation of the GMOs, Pollen Trap Plants and Plant Material

- 40. 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.
- 41. Harvested GMOs, Pollen Trap Plants and Plant Material 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');
 - (b) completely enclosed within a layer of tarpaulin and a layer of shade cloth ('double wrapped in tarpaulin and shade cloth'); or
 - (c) contained within an enclosed chain-bed truck specifically designed for the purpose of transporting cotton modules.
- 42. Cotton lint derived from GMOs and Pollen Trap Plants from ginning is not subject to transportation conditions.
- 43. Every container used to transport the GMOs, Pollen Trap Plants and Plant Material must be labelled:
 - (a) to indicate that it contains genetically modified 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.
- 44. The licence holder must have in place accounting procedures to verify whether the same quantity of GMOs, Pollen Trap Plants or Plant Material sent is delivered and must document routes, methods and procedures used for transportation of GMOs, Pollen Trap Plants and Plant Material.

Contingency Plans

45. Within 30 days of the date of issue 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.
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, Pollen Trap Plants or 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, Pollen Trap Plants and 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.

Reporting

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

Testing methodology

50. 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 the issuing of this licence.

Use of GMOs, Pollen Trap Plants and Plant Material

51. The GMOs, Pollen Trap Plants and Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in their use as food for animals or humans.

DIR No: 058/2005

***Full Title:** Limited and controlled release of insect resistant (VIP) cotton

Organisation Details

Postal address: Deltapine Australia Pty Ltd
PO Box 196
NARRABRI NSW 2390

Phone No: (02) 6793 1300

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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]

Fax: [Personal Information Redacted]

Email Address: [Personal Information Redacted]

Position: [Personal Information Redacted]

Organisation: Deltapine Australia Pty Ltd

Postal Address: PO Box 196
NARRABRI NSW 2390

IBC Details

IBC Name: Deltapine Australia IBC

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

GMOs Description

Purpose of the Dealings with the GMOs:

The aim of the proposed release is to produce seed for future releases (which would be subject to future assessments and approvals).

The GMOs covered by this licence are as follows:

VIP3A cotton

***Parent Organism(s):**

Common Name: Cotton

Scientific Name: *Gossypium hirsutum* L.

***Modified trait:**

Category: Insect resistance

Description: Cotton plants have been genetically modified to be resistant to the major caterpillar pests of cotton. Three lines are authorised for release: COT102, COT202 and COT203.

***Gene(s) responsible for conferring the modified trait:**

vip3A gene from *Bacillus thuringiensis* (insect resistance)

the COT102 line also contains the hygromycin resistance gene *aph4* from *Escherichia coli* (antibiotic resistance)

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