



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 065/2006

Licence holder: Monsanto Australia Limited

Title: Limited and controlled release of insect resistant (Vip3A and/or modified Cry1Ab) GM cotton

Issued: 13 October 2006

Varied: 21 November 2008

Varied: 15 April 2009

Surrendered 16 December 2009

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the 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 nationally consistent regulatory system controlling the development and use of genetically modified organisms (GMOs).

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 Food Standards Australia New Zealand, Australian Pesticide and Veterinary Medicine Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme, National Health and Medical Research Council and Australian Quarantine and Inspection Service. 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.

Dealings permitted by this licence may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Note about where dealings with GMOs are being undertaken pursuant to this

Information about where the GMOs have been planted pursuant to this licence can be found in a separate document entitled 'DIR 065/2006 Site Details'. This document can be viewed by accessing the document on the OGTR website at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir065-2006>.

Section 1 Interpretations and Definitions

In this licence:

- (a) unless defined otherwise in this licence, 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 ninety (90) days of each anniversary of issue 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 Place specified in this licence as requiring Cleaning, the Destruction of the Plant Material in that Place, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of 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 named 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 the 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.

‘Personal information’ means information or an opinion (including information forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

‘Place’ means an area required to be Cleaned and/or inspected under conditions 44 and 48 of this licence.

‘Plant Material’ means any part of the GMOs or non-GM Cotton plants grown at the Location or in the Pollen Trap with respect to that Location, whether viable or not, including, but not limited to, seed, lint, 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 twenty (20) metres in all directions from the outside edge of a Location.

‘Pollen Trap Plant’ means non-GM Cotton.

‘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.

‘Site’ for each Location means the aggregate of all Places in respect of that Location.

‘Volunteer Plants’ means progeny of the GMOs or non-GM Cotton plants grown at the Location or of the Pollen Trap Plants, or regrowth of previous GMOs 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 Monsanto Australia Limited.

Project Supervisor

3. The Project Supervisor in respect of this licence is the person identified in 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 the 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 or otherwise authorised by the licence holder to undertake any activity in connection with the Dealings authorised by 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. Prior to a person covered by this licence conducting any Dealings, the licence holder must obtain signed statements from those persons that the licence holder has informed those people of the conditions of this licence that apply to them and that they have understood the conditions and agree to be bound by them. The licence holder must provide the Regulator, on the Regulator's written request, with copies of these signed statements from persons covered by this licence.

9. The licence holder must notify the project supervisor and all persons covered by a licence that Personal Information collected by the licence holder which is relevant to the administration and/or enforcement of the licence may be released to the Regulator.

Applicant to notify of circumstances that might affect suitability

10. 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

11. 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

12. It is a condition of this licence that the licence holder informs 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.

Note: The Act requires, for the purposes of the above condition that:

- (a) *the licence holder will be taken to have become aware of additional information of a kind mentioned in the above condition if he or she was reckless as to whether such information existed; and*
- (b) *the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in the above condition if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

13. The licence holder must provide the information required by paragraphs (a), (b) and (c) of condition 12 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

14. 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.

15. The licence holder must be able to access and control the Site to the extent necessary to comply with this licence, for the duration of the life of the licence.

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.

Notices

17. The licence holder must provide all notices to the Regulator required to be given by this licence and each notice must be provided in the manner required by Section 6 of this licence.

Section 3 Growing the GMOs

GMO covered by this licence

18. The GMOs covered by this licence are described in Attachment B.

Permitted dealings

19. The permitted dealings with the GMOs are to plant, grow, propagate, harvest 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.

20. Non-GM Cotton may be planted and grown at the Locations, but if planted, must be handled and controlled as if it were a GMO (ie subject to other applicable conditions elsewhere in this licence) and plant material from non-GM plants grown at the Locations must be handled and controlled as if it were Plant Material from the GMOs (ie subject to other conditions elsewhere in this licence).

Locations and size of trial

21. The permitted dealings with the GMOs may be undertaken during the summer cotton growing season in 2006/07 within the shire of Narrabri, NSW.

22. No more than one Location may be used in any one season. The maximum area of the Location must not exceed 1.5 hectares.

Notice of intention to plant and of planting

23. The licence holder must, in the manner required by condition 60, give advance notice to the Regulator of an intention to plant the GMOs.

24. The licence holder must, in the manner required by condition 61, give notice to the Regulator of the actual date of planting the GMOs.

Measures to manage Gene Flow

25. The Location must be surrounded by a Pollen Trap.

26. The 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.

27. The edge of every Pollen Trap that is farthest from the GMOs (the 'outer edge of the Pollen Trap') must not be within fifty (50) metres of a Natural Waterway.

28. Pollen Trap Plants must be handled and controlled as if they were the GMOs (ie subject to other applicable conditions elsewhere in this licence) and Plant Material from Pollen Trap Plants must be handled and controlled as if it were Plant Material from the GMOs (ie subject to other applicable conditions elsewhere in this licence).

Section 4 Use of Plant Material, Cleaning and Disposal of Plant Material

Use of Plant Material

29. With the exception of cotton lint obtained from ginning of Cotton harvested from the GMOs or Pollen Trap or non-GM plants, Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for animals or humans.
30. For avoidance of doubt, cotton lint obtained from ginning of seed Cotton harvested from the GMOs or Pollen Trap or non-GM plants may be sold and is not subject to Transport conditions.

Transportation of Plant Material

31. Subject to conditions 32 and 33, if Plant Material is transported it must be transported according to the OGTR *Guidelines for the Transport of GMOs* as current at the time of transportation.
32. Harvested Plant Material may be transported to a ginning facility in a cotton module that is:
- (a) completely enclosed within two layers of tarpaulin ('double wrapped in tarpaulin');
 - (b) completely enclosed within a layer of tarpaulin inside 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.
33. In addition to the requirements of the above conditions, every container used to transport 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.

Plant Material may be collected

34. Any Plant Material may be collected from a Site for the purpose of conducting experiments on it or any other dealing permitted by this licence.
35. Any experiments with Plant Material other than lint obtained from ginning may only be conducted in a facility certified by the Regulator to at least physical containment level 2 (PC2).
36. Any Plant Material that is collected for the purpose of conducting experiments may be transported off the Site to:
- (a) a facility certified by the Regulator to physical containment level 2 (PC2) for the purpose of conducting experiments on it and/or storage; 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.

Note: Transport of Plant Material must comply with conditions 31 to 33.

37. If Plant Material is experimented with, the Plant Material must be Destroyed on completion of the experiment.

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

Notice of Harvest and Cleaning following harvest

38. The licence holder must, in the manner required by condition 62, provide the Regulator with a notice of intention to harvest the GMOs at the Location.

39. The licence holder must, in the manner required by condition 63, provide the actual date or dates of harvesting of the GMOs at the Location.

Harvest and post-harvest procedures

40. If the GMOs or non-GM plants grown at the Location or Pollen Trap Plants are harvested, they must be harvested separately from any other crop.

41. If seed Cotton harvested from the GMOs or non-GM plants grown at the Location or Pollen Trap Plants is ginned, it must be ginned separately from any other crop.

42. Following ginning, seed from the GMOs and non-GM plants grown at the Location 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) replanted subject to the conditions of this licence or other relevant authorisation under the Act; or
- (d) Destroyed.

Note: Transport of Plant Material must comply with conditions 31 to 33.

Cleaning – post harvest and generally

43. Cleaning of Equipment must occur immediately or as soon as practicable after use and before it is used for any other purpose (eg if GM seed is ginned, the gin must be Cleaned immediately following its use and before any other crop is ginned).

44. The following Places must be Cleaned in accordance with these licence conditions:

- (a) the Location and the Pollen Trap;
- (b) any areas used to gin Plant Material;
- (c) any areas used to Clean Equipment used in connection with Plant Material at the Location and the Pollen Trap or to Destroy Plant Material.

45. Each Place must be Cleaned either within fourteen (14) days of harvest of the GMOs or within nine (9) months of planting of the GMOs, whichever occurs first.

46. The licence holder must, in a manner required by condition 64, give notice to the Regulator of the date on which Cleaning of the Place concluded.

Section 5 Use of Site, Inspection and Sign off

General conditions on use of Locations post-harvest

47. If the GMOs are grown at a Location, no plants may be planted at the Location, or the 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.

Inspection

48. Following Cleaning of a Location or other areas, 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 Plant Material or to Destroy Plant Material.

49. Inspection must be performed by a person who is able to recognise Volunteer Plants.

50. Any Volunteer plant must be Destroyed prior to the plant flowering.

51. For the Location, all the Places required to be inspected must be inspected at least once every two (2) months, commencing on the last day of Cleaning of the Location and continuing until the Regulator has issued a Sign-off for the relevant Site.

52. The results of inspection activities must be recorded in a logbook or paper file. The licence holder must, in the manner required by condition 66, provide the Regulator with the findings of the inspections as recorded in the logbook or paper file.

53. Inspection conditions do not apply in respect of a Place if the licence holder has received a Sign-off for that Place.

Sign off

54. For each Site,

- (a) if inspections have been routinely completed for a period of at least twelve (12) months, and,
- (b) if inspection records for that Site show that no Volunteers have been observed in the most recent six (6) month inspection period,
- (c) the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site.

Section 6 Reporting and Documentation Requirements

Compliance Management Plan

55. Prior to growing the GMOs, a written Compliance Management Plan must be provided to the Regulator. The Compliance Management Plan must describe in detail

how the licence holder intends to ensure compliance with each of these conditions and document that compliance and must include:

- (a) A list of the names of all organisations or natural persons who will be persons covered by this licence. Where a name of a person is not known at the time of submitting the Compliance Management Plan the function or position of the person to be covered must be provided.

Note: Examples of functions or positions are 'Site manager', 'Farm labourer' etc.

- (b) An explanation of how the licence holder has informed, or proposes to inform, each person intended to be covered by the licence of the conditions of this licence including conditions related to the collection of personal information by the licence holder from the person intended to be covered by the licence.
- (c) A description of the responsibilities of the licence holder and of each person covered by the licence in relation to the requirements of this licence.
- (d) A description of how any contracts, agreements, or other enforceable arrangements between the licence holder and persons covered by the licence will allow the licence holder to access and control a Site to the extent necessary to comply with this licence, for the duration of the life of the licence.
- (e) A description of the licence holder's plans for post harvest use of a Site during the life of this licence.

56. Where any of the details of the compliance management plan change, the Regulator must be notified of the changes within fourteen (14) days of the change occurring.

Contingency Plans

57. Within thirty (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 Plant Material outside the Site relevant to the Location.

58. 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 Plant Material found outside of the Site; and
- (c) inspect for and Destroy any Volunteer Plants that may exist as a result of the event.

59. If an unintended presence of Plant Material is discovered outside the Site, the Contingency Plan must be implemented.

Notice of intention to plant and of planting

60. At least seven (7) days prior to the date on which planting of the GMOs is intended to commence, 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-GM cotton on the Location is intended to commence;
- (c) details of the Location where the GMOs will be planted, including the size of the Location, 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);
- (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 Site; and
- (g) a description of how the Site is intended to be used during the first two years following harvest of the GMOs.

61. Within seven (7) days of planting of the GMOs, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the actual date on which planting of the GMOs occurred;
- (b) details of the Location where the GMOs were planted, including the size of the Location, a street address and GPS coordinates for the Location;
- (c) the period during which the licence holder considers the GMOs are likely to flower;
- (d) the period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed in lieu of harvest); and
- (e) a description of how the Site is intended to be used during the first two years following harvest of the GMOs.

Notice of harvest and Cleaning following harvest

62. The licence holder must provide the Regulator with a notice of intention to harvest the GMOs at the Location. This notice must be provided at least seven (7) days, and not more than twenty one (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.

63. The licence holder must provide the actual date or dates of harvesting of the GMOs at the Locations within seven (7) days of completion of harvesting of the GMOs at the Locations.

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

65. 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.

Results of inspection activities

66. 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 fourteen (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 current land use (eg type of crop being grown) and of recent land management practices (eg cultivation or spraying) applied in the areas inspected;
- (c) details of the date of inspection;
- (d) 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;
- (e) the means of inspection used;
- (f) the number of Volunteer Plants observed, if any;
- (g) details of the development stages reached by the Volunteer Plants, if any;
- (h) details of methods used to Destroy Volunteer Plants, if any.

Transportation of Plant Material

67. The licence holder must have in place accounting procedures to ensure the same quantity of Plant Material sent is delivered and must document routes, methods and procedures used for transportation of Plant Material.

Annual Report

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

Testing methodology

69. 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 (for details see Attachment B) in a recipient organism. The instrument must be provided within thirty (30) days of the issuing of this licence.

ATTACHMENT A

DIR No: 065/2006

***Full Title:** Limited and controlled release of GM insect resistant (VIP3A and/or modified Cry1Ab) cotton

Organisation Details

Postal address: Monsanto Australia Ltd
Level 12, 600 St Kilda Road
Melbourne VIC 3004

Phone No: (03) 9522 7122

Fax No: (03) 9522 6122

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: Monsanto Australia Ltd

Postal Address: Monsanto Australia Ltd
Level 12, 600 St Kilda Road
Melbourne VIC 3004

IBC Details

IBC Name: Monsanto IBC

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

GMO Description

***Parent Organism(s):**

Common Name: Cotton

Scientific Name: *Gossypium hirsutum* L.

***Modified trait:**

Category: Insect and antibiotic resistance

Description: Cotton plants have been genetically modified for enhanced resistance to certain lepidopteran insects

***Genes responsible for conferring the modified trait:**

vip3A gene from *Bacillus thuringiensis*

modified *cry1Ab* gene from *B. thuringiensis*

aph4 gene from *Escherichia coli*

Purpose of the Dealings with the GMOs:

This licence is for a release of 11 lines of insect resistant GM cotton into the environment on a limited scale and under controlled conditions. The purpose of the trial is to conduct early stage research and to produce seed from the GM cotton lines for use in further studies in future trials (subject to future applications and approvals).

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