



**Australian Government**

**Department of Health and Ageing**

**Office of the Gene Technology Regulator**

# **Licence for dealings involving an intentional release of a GMO into the environment**

**Licence No.: DIR 087**

**Licence holder: Bayer CropScience Pty Ltd**

**Title: Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance**

**Issued: 8 December 2008**

**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).

This licence is issued by the Gene Technology Regulator in accordance with the Gene Technology Act 2000 and, as applicable, Corresponding State Law.

The Gene Technology Regulator is required to consult with, and take into account advice from a range of key stakeholders, including other 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.

The licence authorises the licence holder and persons covered by the licence to conduct specified dealings with the genetically modified organism(s) listed in Attachment B of this licence.

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.

## **Section 1 Interpretations and Definitions**

1. 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.
2. 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 with respect to 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.

**‘Cultivate’** means the following:

- (a) till the soil in a manner suitable for the germination of Cotton seed; and
- (b) provide adequate soil moisture to promote the germination of Cotton seed.

**‘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; or
- (c) ploughing; or
- (d) burning; or
- (e) treatment with herbicide; or
- (f) hand weeding; or
- (g) autoclaving; or
- (h) burial under at least 1 metre of soil.

*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 the subject of the dealings authorised by this licence.

**'Location'** means the area of land where the GMOs or other plants may be intentionally planted and grown pursuant to this licence, but does not include the Pollen Trap.

**'Natural Waterway'** 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 the conditions of this licence.

**'Plant Material'** means the whole, or 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 or GM cotton approved under DIR 066/2006.

**'Sign-off'** means a notice in writing from the Regulator, with respect to a Site, that post harvest inspection conditions no longer apply with respect to that Site.

**'Site'** for each Location means the aggregate of all Places with respect to that Location.

**‘Volunteer Plants’** means progeny of the GMOs or non-GM Cotton plants grown at the Location or of the Pollen Trap Plants with respect to the Location, or regrowth of previous GMOs or non-GM Cotton plants.

## **Section 2 General conditions**

### ***Duration of Licence***

3. 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***

4. The holder of this licence (‘the licence holder’) is Bayer CropScience Pty Ltd (Bayer).

### ***Project Supervisor***

5. The project supervisor with respect to this licence is the person identified in Attachment A of the licence.

6. 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***

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

### ***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 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***

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. If a particular condition, including any variation of it, applies to a person with respect to a particular dealing, the licence holder must not permit a person covered by this licence to conduct that dealing unless,

- (a) the person has been informed of the condition, including any variation of it, and
- (b) the licence holder has obtained from the person a signed and dated statement that the person,
  - i) has been informed by the licence holder of the condition and, when applicable, its variation, and
  - ii) has understood and agreed to be bound by the condition, or its variation, and

iii) has not conducted the dealing without being informed of the condition, or its variation.

11. The licence holder must provide the Regulator, on the Regulator's written request, with copies of the signed and dated statements referred to in the immediately preceding condition.

12. 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***

13. 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***

14. 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***

15. 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.*

16. 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***

17. 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.

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

***Remaining an Accredited organisation***

19. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and comply with its instrument of accreditation.

***Notices***

20. 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 7 of this licence.

***Section 3 Growing the GMOs***

***GMOs covered by this licence***

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

***Permitted dealings***

22. The permitted dealings with the GMOs are to plant, grow, propagate, harvest, transport and dispose of the GMOs, to conduct experiments with the GMOs, and the possession, supply and use, of the GMOs for the purpose of any of the permitted dealings with the GMOs, or in the course of any of these dealings.

***Non-GM Plants***

23. Non-GM Cotton may be planted and grown at the Location but, if planted, must be handled and controlled as if it were the GMO (ie subject to other applicable conditions elsewhere in this licence).

24. Plant Material from non-GM Cotton grown at a Location must be handled and controlled as if it were Plant Material from the GMO (ie subject to other conditions elsewhere in this licence).

***Limits – location, growing season and size of trial***

25. With respect to the permitted dealings described in condition 22, planting, growing, propagating and harvesting must only be undertaken over a single cotton growing season (2008-2009), within the New South Wales local government area of Narrabri.

26. No more than one Location can be planted. The maximum area for intentional planting is 0.36 hectares.

### **Notice of intention to plant and of planting**

27. The licence holder must, in the manner required by paragraph 69, give advance notice to the Regulator of an intention to plant the GMOs.
28. The licence holder must, in the manner required by paragraph 70, give notice to the Regulator of the actual date of planting the GMOs.

### **Controls – planting and growing**

29. Each Location must be surrounded by a Pollen Trap.
30. Each Pollen Trap must be planted and maintained in a way that ensures that for the duration of flowering of the GMO(s) there is a continuous barrier of plants at least twenty (20) metres deep in all directions around the Location.
31. 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.
32. 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.
33. 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**

### **Experiment and storage**

34. Experiments and/or analysis of Plant Material is only permitted if:
- (a) the experiment and/or analysis is a notifiable low risk dealing; and
  - (b) the experiment and/or analysis does not involve the feeding of the Plant Material to humans or animals.

*Note: A dealing will only be a notifiable low risk dealing if:*

- (a) *an Institutional Biosafety Committee has been asked to assess whether the proposed Dealing is a notifiable low risk dealing; and*
  - (b) *the Committee has assessed the proposed dealing to be a notifiable low risk dealing; and*
  - (c) *the person who proposes to undertake the proposed dealing and the project supervisor for the proposed dealing have been notified that the Committee;*
    - i) has assessed the proposed dealing to be a notifiable low risk dealing; and*
    - ii) considers that the personnel to be involved in the proposed dealing have appropriate training and experience.*
35. Any Plant Material may be collected from the Site for the purpose of conducting experiments and/or analysis on it or any other dealings permitted by this licence.
36. Any Plant Material that is collected for experiments and/or analysis may be transported off the Site for the purpose of conducting experiments on it.

37. Any Plant Material that is collected for experiments and/or analysis may be transported off Site 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, analysed and stored in any one or more of these facilities.

38. Plant Material or waste derived from experiments must be Destroyed as soon as practicable.

***Plant Material not to be used in food***

39. The GMOs 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.

***Section 5 Transport, Cleaning and Disposal***

40. If GMOs are Destroyed, they are taken to have been harvested for the purposes of this licence and all conditions applying to post-harvest apply equally to post-Destruction.

***Notice of Harvest and Cleaning following harvest***

41. The licence holder must, in the manner required by condition 71, provide the Regulator with a notice of intention to harvest the GMOs at each Location.

42. The licence holder must, in the manner required by condition 72, provide the actual date or dates of harvesting of the GMOs at each Location.

43. The licence holder must, in a manner required by condition 73, give notice to the Regulator of the date on which Cleaning of each Place concluded.

***Harvest and post harvest procedures***

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

45. 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.

46. Following ginning, seed from the GMOs and non-GM plants grown at the Location and Pollen Trap Plants must only be:

- (a) stored in a sealed container, within a locked facility (PC2 or that approved in writing by the Regulator) that is signed so as to indicate that GM Cotton seed is stored within the facility; or
- (b) experimented on within a facility as specified in conditions 34 and 37; or
- (c) exported; or
- (d) replanted subject to the conditions of this licence or other relevant authorisation under the Act; or
- (e) destroyed.

### ***Transportation of Plant Material***

47. Any Plant Material transported, other than Harvested Plant Material, must be transported in accordance with the guidelines for the transportation of GM Plant Material found in the OGTR *Guidelines for the Transport of GMOs* as current at the time of transportation, and routes, methods and procedures used for this transportation in accordance with this licence must be documented and provided to the Regulator on request.
48. 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.
49. 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 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.

### ***Cleaning of Equipment and Places***

50. 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).
51. The following Places must be Cleaned in accordance with these licence conditions:
- (a) each Location and the Pollen Trap with respect to each Location;
  - (b) irrigation channels and drains through which water flows to and from the Location;
  - (c) any areas used to gin Plant Material;
  - (d) any areas used to Clean Equipment used in connection with the GMOs or Plant Material at each Location and the Pollen Trap with respect to each Location or to Destroy the GMOs or Plant Material.
52. Each Place with respect to each Location 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.

### ***Section 6 Inspection, Use of Site and Sign-off***

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

### ***Inspection***

54. Following Cleaning of a Place, the following Places must be inspected for the existence of Volunteer Plants:
- (a) the Location;
  - (b) the Pollen Trap with respect to the Location;
  - (c) irrigation channels and drains through which water flows to and from each Location and the Pollen Trap with respect to each Location;
  - (d) any areas used to Clean Equipment used in connection with Plant Material or to Destroy Plant Material.
55. Any Volunteer Plant must be Destroyed prior to the plant flowering.
56. For each 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.
57. The licence holder must, in the manner required by condition 75, provide the Regulator with the findings of the inspections.
58. Inspection conditions do not apply with respect to a Place within a Site if the licence holder has received a Sign-off for that Site.

### ***Cotton seed bank reduction***

59. In the first spring or summer season following the final harvest of the GMOs, the licence holder must Cultivate each Location and Pollen Trap with respect to that Location so as to promote the germination of Volunteer Plants.
60. If, in Cultivating the Location and Pollen Trap with respect to that Location, the soil does not contain sufficient moisture through accumulated rainfall or irrigation to cause the germination of Volunteer Plants, the licence holder must ensure that the Location and Pollen Trap with respect to that Location is irrigated sufficiently to cause the germination of Volunteer Plants.

### ***General conditions on use of Locations post harvest***

61. If the GMOs are grown at a Location, no plants may be planted at the Location, or the Pollen Trap with respect to the Location, until inspection obligations are completed unless:
- (a) the plants are included in the OGTR policy on post-harvest crops at the time of planting (refer to table that specifies the post-harvest crops permitted for GM Cotton field trials at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/policies-1>);
  - (b) the plants are the GMOs or non-GM Cotton planted in accordance with the conditions of this licence as they apply to GMOs and non-GM Cotton plants; or
  - (c) the plants are plants agreed to in writing by the Regulator.

### ***Sign-off***

62. 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 Volunteer Plants have been observed in the most recent six (6) month inspection period,

the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site and that the site receive 'Sign-off'.

## **Section 7 Reporting and Documentation Requirements**

### **Compliance Management Plan**

63. 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.

64. 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 Plan**

65. 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 each Location.

66. 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;
- (c) inspect for and Destroy any Volunteer Plants that may exist as a result of the event.

67. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs or Plant Material is discovered outside an area that must be inspected.

68. If for any reason the licence holder cannot implement the Contingency Plan when required to do so, the licence holder must notify the Regulator as soon as is reasonably practicable.

***Notice of intention to plant and of planting***

69. 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(s) on which planting of the GMOs and Pollen Trap Plants is intended to commence;
- (b) the date(s) 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 and Pollen Trap Plants are likely to flower;
- (e) the period during which the licence holder considers the GMOs and other plants authorised by this licence are likely to be harvested (or Destroyed in lieu of harvest);
- (f) if GMOs have previously been planted at a Location or within the Pollen Trap with respect to that Location, a history indicating how the Location and the Pollen Trap with respect to that Location have been used in the preceding two years, including details of previous GMOs and post harvest crops planted at the Location and the Pollen Trap with respect to that Location; and
- (g) a description of how the Location and the Pollen Trap with respect to that Location are intended to be used during the first two years following harvest of the GMOs.

70. 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(s) on which planting of the GMOs and Pollen Trap Plants occurred;
- (b) the actual date(s) on which planting of any non-GM Cotton plants on the Location occurred;
- (c) details of the Location where the GMOs were 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 and Pollen Trap Plants are likely to flower;
- (e) the period during which the licence holder considers the GMOs and other plants authorised by this licence are likely to be harvested (or Destroyed in lieu of harvest); and

- (f) a description of how the Location and the Pollen Trap with respect to that Location are intended to be used during the first two years following harvest of the GMOs.

***Notice of harvest and Cleaning following harvest***

- 71. 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.
- 72. The licence holder must provide the actual date or dates of harvesting of the GMOs at the Locations. This notice must be provided within seven (7) days of completion of harvesting of the GMOs at the Locations.
- 73. 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.
- 74. 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***

- 75. 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 any rainfall events at the location including measurements of any rainfall;
  - (d) details of the date of inspection;
  - (e) 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;
  - (f) the means of inspection used;
  - (g) the number of Volunteer Plants observed, if any;
  - (h) details of the development stages reached by the Volunteer Plants, if any;
  - (i) details of methods used to Destroy Volunteer Plants, if any; and
  - (j) if Volunteer Plants were found, the actual date(s) of Destruction, which must be confirmed within fourteen (14) days of Destruction.
- 76. The licence holder must keep a record of the area planted to the GM cotton.

**Annual Report**

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

**Testing methodology**

78. The licence holder must provide a written instrument to the Regulator describing an experimental method that is capable of reliably and specifically 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: 087**

**\*Full Title:** Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance

### **Organisation Details**

**Organisation:** \*Bayer CropScience Pty Ltd

**Postal address:** Bayer CropScience Pty Ltd  
391-393 Tooronga Road  
HAWTHORN EAST VIC 3123

**Phone No:** (03) 9248 6833

**Fax No:** (03) 9248 6605

### **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:** *[Personal Information Redacted]*

**Postal Address:** PO Box 1251  
GOONDIWINDI  
QLD 4390

### **IBC Details**

**IBC Name:** Bayer CropScience 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(s):**Category: Insect resistance  
Herbicide tolerance

Description: The GM cotton contains two genes coding for insecticidal delta-endotoxins. Expression of the genes in cotton should confer resistance to lepidopteran insect pests.

The GM cotton also contains a gene encoding the enzyme phosphinothricin acetyltransferase (PAT) which provides tolerance to herbicides containing glufosinate ammonium.

**\*Genetic elements responsible for conferring the modified traits:**Insect resistance *Cry IAb* and *cry2Ae* gene sequences derived from the bacterium *Bacillus thuringiensis* and codon modified for expression in plants.Herbicide tolerance Two copies of the *bar* gene from the bacterium *Streptomyces hygroscopicus*.**Purpose of the Dealings with the GMOs:**

Bayer applied for a licence to release genetically modified (GM) cotton into the environment on a limited scale and under controlled conditions. The purpose of the trial is to conduct research to evaluate the agronomic performance of the GM cotton plants and to assess the efficacy of the insecticidal protein combination against *Helicoverpa armigera* (cotton bollworm). None of the GM plant material from the trial will be used in human food, animal feed or for the production of fabrics and/or other cotton products

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