



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

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

**Licence No.: DIR 113**

**Licence holder: Bayer CropScience Pty Ltd**

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

Issued: 30 April 2012  
Varied: 15 October 2012  
Varied 12 July 2013  
Varied 9 August 2013  
Varied 14 March 2014  
Varied 6 February 2015  
Varied 24 December 2015  
Varied 15 January 2016

**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, 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 Pesticides and Veterinary Medicines 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 A 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.

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

Information about where the GMOs have been planted pursuant to this licence can be accessed on the OGTR website on [DIR 113 page](#).

## **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, words and phrases used 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.

3. In this licence:

**'Act'** means the *Gene Technology Act 2000* (Commonwealth) or the corresponding State legislation under which this licence is issued.

**'Burial site'** means a place where the GMO or Plant Material is Destroyed by burial.

**'Clean'** means, as the case requires:

- (a) in relation to an area specified in this licence as requiring Cleaning, the Destruction of the GMOs and Plant Material in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs and Plant Material from the Equipment, to the reasonable satisfaction of the Regulator.

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

**'Cultivate'** means the following:

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

**'Destroy'** 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/incineration; or

- (e) treatment with herbicide; or
- (f) hand weeding; or
- (g) autoclaving; or
- (h) burial, but only subject to the conditions of this licence; or
- (i) root cutting and mulching/slashing; or
- (j) a method approved in writing by the Regulator.

*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, but is not limited to, harvesters, seeders, storage equipment, transport equipment (eg bags, containers, trucks), clothing and tools.

**'Exclusion Zone'** means an area extending at least 1.5 kilometres in all directions from the outer edge of a Location.

**'Flowering'** is taken to begin when any plant of the class of plants referred to in a particular condition first flowers, and is taken to end when all plants in the class of plants no longer have flowers.

**'GM'** means genetically modified.

**'GMOs'** means the genetically modified organisms that are the subject of the dealings authorised by this licence.

**'Location'** means an area of land where the GMOs are intentionally planted and grown pursuant to this licence, but does not include the Pollen Trap.

**'Logbook'** means a written or electronic record containing information required to be collected and maintained by this licence and which is able to be presented to the OGTR on request.

**'Monitoring Zone'** means an area of land extending at least 100 metres in all directions from the outer edge of a Location.

**'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.

**'Plant Material'** means any part of the GM or non-GM Cotton plants grown at a Location or in the Pollen Trap with respect to a Location, whether viable or not, including, but not limited to, seed, stubble, lint 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 outer edge of a Location.

**'Pollen Trap Plant'** means non-GM Cotton, or GM Cotton approved under licences DIR 062/2005 or DIR 066/2006, grown in a Pollen Trap.

**'Regulator'** means the Gene Technology Regulator.

**‘Sign-off’** means a notice in writing from the Regulator, in respect of a Site, that post-harvest obligations no longer apply in respect of that Site.

**‘Site’** means a Location and the aggregate of areas requiring post-Cleaning inspections in respect of that Location.

**‘Volunteers’** means GM or non-GM Cotton plants, which have not been intentionally grown on the Site.

**‘Waterways’** means all permanent natural waterways and man-made waterways that flow into natural waterways.

*Note: Irrigation channels, holding dams or storage ponds that do not flow into natural waterways are not considered Waterways for the purpose of this licence.*

## **Section 2 General conditions**

### **Duration of licence**

4. 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**

5. The holder of this licence ('the licence holder') is Bayer CropScience Pty Ltd.

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

### **Project supervisor**

7. 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**

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

### **Persons covered by this GMO licence**

9. 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**

10. 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.

11. 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.

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

13. Prior to growing the GMOs, the licence holder must provide the Regulator with an explanation of how the licence holder has informed, or proposes to inform, each person intended to be covered by this licence of the conditions of the licence, including conditions related to the collection of Personal Information by the licence holder.

14. Where any of the details provided under the immediately preceding condition change, the licence holder must notify the Regulator of the changes within 14 days of the change occurring.

15. The licence holder must notify the project supervisor and all persons covered by the 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.

***Additional information to be given to the Regulator***

16. 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; and
- (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; and
- (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.

17. 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.

18. The licence holder must 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.

*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 paragraph 18(a) 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 paragraph 18(b) if he or she was*

*reckless as to whether such contraventions had occurred, or such unintended effects existed.*

*Note: Contraventions of the licence may occur through the action or inaction of a person. For example if it is a condition of the licence that volunteers are destroyed prior to reaching maturity and a volunteer reaches maturity, then the person responsible for controlling volunteers will have contravened that licence condition.*

19. If the licence holder is required to inform the Regulator under the immediately preceding condition, the Regulator must be informed without delay.

*Note: An example of informing without delay is contact made at the time of the incident via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location if required.*

20. If the licence holder informs the Regulator under the immediately preceding condition and the Regulator requests further information, the further information must be provided in a manner, and within the time period, stipulated by the Regulator.

21. Prior to growing the GMOs, the licence holder must provide to the Regulator:

- (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 list, the function or position of the person to be covered must be provided, and
- (b) 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.

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

22. Where any of the details provided under the immediately preceding condition change, the Regulator must be notified of the changes within 14 days of the change occurring.

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

23. If a person is authorised by this licence to deal with the 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.

24. The licence holder must be able to access all Exclusion Zones, if any, and to access and control all Sites, Monitoring Zones, if any, approved facilities or other premises to the extent necessary to comply with this licence, for the duration of the life of the licence.

25. Prior to growing the GMOs, the licence holder must provide to the Regulator a description of how any contracts or other enforceable arrangements will allow the licence holder to access and control all Sites, Monitoring Zones, Exclusion Zones, approved facilities or other premises to the extent necessary to comply with this licence, for the duration of the life of the licence.

26. Where any of the details provided under the immediately preceding condition change, the licence holder must notify the Regulator of the changes within 14 days of the change occurring.

## **Section 3 Growing the GMOs**

### **GMOs covered by this licence**

27. The GMOs covered by this licence are described in Attachment A.

### **Permitted dealings**

28. The permitted dealings with the GMOs are to conduct experiments with the GMOs, import, breed, propagate, grow, culture, transport and dispose of the GMOs, and the possession, supply and use of the GMOs in the course of any of these dealings.

### **Plants that may be grown at Locations**

29. The only plants permitted to be grown at a Location are:

- (a) the GMOs; or
- (b) non-GM Cotton; or
- (c) GM Cotton approved under licences DIR 062/2005 or DIR 066/2006.

### **Handling of Plants other than the GMOs**

30. Non-GM Cotton or GM Cotton approved under licences DIR 062/2005 or DIR 066/2006 grown at a Location, and Plant Material from these plants must be handled and controlled as if they were the GMOs or Plant Material from the GMOs.

### **Limits - location, timing and size of trial**

31. With respect to the permitted dealings described in condition 28, breeding, propagating, growing and culturing must only be undertaken between May 2012 and May 2016, inclusive, in the local government areas of Narrabri, Moree Plains, Walgett and Gunnedah, NSW, Wyndham-East Kimberley, WA, and Central Highlands, Western Downs, Toowoomba and Balonne, Qld.

32. Intentional planting and growing of the GMOs must occur at no more than ten Locations per year. The area of each Location must not exceed 1 hectare in the period from May 2012 – April 2013 and must not exceed 6 hectares in the period from May 2013 – May 2016.

### **Containment measures**

33. Each Location must be:

- (a) surrounded by a Monitoring Zone and an Exclusion Zone; or
- (b) surrounded by a Pollen Trap.

34. If a Monitoring Zone and an Exclusion Zone are used in accordance with the previous condition:

- (a) the outer edge of the Location must not be within 50 metres of a Waterway; and
- (b) while the GMOs are being grown at the Location, the Monitoring Zone must be maintained in a manner appropriate to allow the identification and/or Destruction of Cotton plants; and
- (c) the GMOs must not be planted in a Location if any cotton crop, other than a crop planted pursuant to this licence, is present in the Exclusion Zone.

35. If a Pollen Trap surrounds a Location;

- (a) the outer edge of the Pollen Trap must not be within 50 metres of a Waterway; and



- (b) the Pollen Trap must be planted only to Pollen Trap Plants and maintained in such a way as to:
  - i. reasonably promote a dense and vigorous growth of the Pollen Trap Plants; and
  - ii. ensure that the Pollen Trap Plants flower at the same time and for the same period of time as the GMOs; and
  - iii. ensure that for the duration of flowering of the GMOs there is a continuous barrier of plants at least 20 metres deep in all directions around the Location, although allowance may be made for a path of approximately 2.5 metres in width in order to access the Location; and
- (c) Pollen Trap Plants and Plant Material from Pollen Trap Plants must be handled and controlled as if they were the GMOs or Plant Material from the GMOs.

## **Section 4 Transport, Storage and Use**

### **Transport and storage**

36. If transport or storage is not conducted in accordance with notifiable low risk dealing (NLRD) requirements, it must be conducted in accordance with Conditions 37, 38 and 39.

*Note: Dealings conducted in accordance with NLRD requirements must be assessed by an IBC before commencement and must comply with the requirements of the Gene Technology Regulations 2001.*

37. Transport and storage of Plant Material must:

- (a) only occur to the extent necessary to conduct the dealings permitted by this licence or other valid authorisation; and
- (b) be in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* for PC2 GM plants as current at the time of transportation or storage, subject to Condition 38.

38. If harvested Plant Material is transported in a cotton module, the cotton module must be:

- (a) completely enclosed within two 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'); or
- (c) contained within an enclosed chain-bed truck specifically designed for the purpose of transporting cotton modules; and
- (d) labelled as detailed in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as current at the time of transportation.

39. Methods and procedures used for any transportation of Plant Material must be recorded by the licence holder, and must be provided to the Regulator, if requested.

### **Use of Plant Material**

40. Plant Material collected or harvested from a Location may be used for experimentation or analysis provided the experimentation and analysis takes place:

- (a) within a Location; or
- (b) in a facility approved in writing by the Regulator.

41. 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 feed for animals or food for humans.

### **Section 5 Harvest, Cleaning and Disposal**

42. If GMOs at a Location 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.

43. If the GMOs are harvested, they must be harvested separately from any other crop.

44. If seed Cotton harvested from the GMOs is ginned, it must be ginned separately from any other crop, and the gin must be Cleaned immediately following its use and before any other crop is ginned.

45. Cleaning of Equipment used in connection with the GMOs must occur as soon as practicable after use and before it is used for any other purpose.

46. The following places must be Cleaned:

- (a) each Location and the Pollen Trap (if any) in respect of each Location; and
- (b) any areas where Plant Material has been dispersed during growing or harvesting; and
- (c) any areas used to Clean Equipment used in connection with the GMOs; and
- (d) any areas used to Destroy Plant Material; and
- (e) any areas used to store or experiment on Plant Material.

47. Places requiring Cleaning other than the Location and Pollen Trap must be Cleaned as soon as practicable after use and before they are used for any other purpose.

48. The Location and Pollen Trap (if any) must be Cleaned either within 28 days of harvest of the GMOs or within 9 months of planting of the GMOs, whichever occurs first.

*Note: Other conditions of this Licence require the licence holder to make records and give notices to the Regulator in relation to Cleaning (Section 8 – Reporting and Documentation Requirements).*

48A. If Destruction of Plant Material occurs by burial, the licence holder must:

- (a) bury Plant Material in a pit dug into the ground in such a way that the Plant Material is covered by a layer of soil at least 1 m in depth, the top of which is no higher than the soil surface surrounding the Burial site; and
- (b) within 14 days of burial, provide the Regulator a written notice indicating the precise location of the Burial site (GPS coordinates and either a street address or other directions) and the date on which burial occurred; and
- (c) subject to Condition 48B, inspect the Burial site at least once every 2 months until Sign-off, to identify Volunteers and any significant disturbance that may affect the emergence of Volunteers, and:
  - i) if disturbance is identified, take appropriate remedial action and notify the Regulator of the disturbance and the remedial action taken; and
  - ii) if Volunteers are identified, Clean the Burial site as soon as practicable.

*Note: Results of inspection activities are required to be recorded in a Logbook and provided to the Regulator (Conditions 68 and 69).*

48B. Monitoring and Sign-off of the Burial site is not required if burial takes place at a Municipal or commercial land fill and the Regulator is provided with a written notice from the manager of the land fill undertaking:

- (a) to bury the plant material on the day of delivery; and
- (b) not to disturb the Burial site for a period of at least 1 year from the date of burial; and
- (c) to notify both the licence holder and the Regulator in writing of any significant disturbance of the Burial site.

## **Section 6 Conditions on use of Sites after harvest**

### **General conditions on use of Location and other areas requiring inspection post-harvest**

49. After harvest of GMOs in a Location, no plants may be planted at the Site unless:
- (a) the plants are listed as permitted 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>); or
  - (b) the plants are the GMOs or other Cotton planted in accordance with the conditions of this licence; or
  - (c) the plants are plants agreed to in writing by the Regulator; or
  - (d) the Regulator has issued a Sign-off for the Site.
50. Following Cleaning, all areas of a Site must be maintained in a manner appropriate to allow the identification of Volunteers for as long as inspections are required.

### **Cotton seed bank reduction**

51. In the first spring or summer season following the harvest of the GMOs at each Location, the licence holder must Cultivate the Location and Pollen Trap (if any).

*Note: Any Volunteers must be Destroyed (see Section 7 regarding inspections).*

## **Section 7 Inspections**

52. Inspections must be performed by a person who is able to recognise Volunteers.

### **Inspections during growing of the GMOs at a Location**

53. Each Monitoring Zone, if any, must be inspected for volunteers at least once every 35 days from 14 days prior to the expected commencement of Flowering of any GMOs\* until all GMOs have been harvested or Destroyed, and any Cotton plants in the Monitoring Zone Destroyed before Flowering.

54. Each Exclusion Zone, if any, must be inspected for intentionally planted cotton at least once every 35 days from 14 days prior to the commencement of Flowering of any GMOs\* until all GMOs have finished Flowering, and if any intentionally planted Cotton is present within the Exclusion Zone, other than pursuant to this licence, either the intentionally planted Cotton or the GMOs in the Location must be Destroyed before Flowering.

*\*Condition 63 requires the licence holder to provide information to the Regulator on the expected flowering period, however the inspection period should be based on the observed development of the GMOs, so that inspections commence prior to any GMOs flowering.*

*Note: Details of any inspection activity under Conditions 53 and 54 must be recorded in a Logbook as detailed in Condition 68.*

### **Post-Cleaning inspections**

55. Following Cleaning of a Location, the following areas must be inspected for the existence of Volunteers:

- (a) the Location;
- (b) the Pollen Trap, if any;
- (c) any areas in which Volunteers may be able to establish, including, but not limited to areas:
  - i. onto which Plant Material was dispersed during growing or harvesting; or
  - ii. that were used to Clean Equipment used in connection with Plant Material; or
  - iii. that were used to Destroy Plant Material; or

*Note: If seeds may have dispersed into irrigation channels and drains through which water flows to and from the Location and the Pollen Trap, these are likely areas in which Volunteers may establish.*

56. For each Location, the Site must be inspected at least once every 35 days, commencing on the last day of Cleaning of the Location and continuing until:

- (a) the Location is replanted to the GMOs in accordance with this licence; or
- (b) the Location is planted to the GMOs in accordance with DIR 133; or
- (c) the Regulator has issued a Sign-off for the relevant Site.

57. Any Volunteers must be Destroyed prior to Flowering.

58. Inspection conditions do not apply with respect to any area within a Site if the licence holder has received a Sign-off for that Site.

*Note: Results of inspection activities are required to be provided to the Regulator (see Section 8 – Reporting and Documentation Requirements).*

### **Sign-off**

59. The licence holder may make written application to the Regulator that inspection conditions no longer apply to a Site if:

- (a) inspections have been routinely completed for a period of at least 12 months; and
- (b) inspection records for the Site show that no Volunteers have been observed in the most recent 6 month inspection period.

*Note: Licence conditions require Cultivation for each Location and Pollen Trap, if any, prior to a Sign-off application (see Section 6 – Conditions on use of Sites after harvest). The Regulator will take into account the management and inspection history for the Site, including tillage, irrigation, and rainfall and occurrence of volunteers, in deciding whether or not he is satisfied that no further inspections are required to manage persistence of the GMOs.*

## **Section 8 Reporting and Documentation Requirements**

### **Contingency Plan for unintended presence of Plant Material**

60. 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 or Plant Material outside an area that must be inspected.
61. 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; and
  - (b) recover and Destroy any of the GMOs or Plant Material; and
  - (c) inspect for and Destroy any Volunteers that may exist as a result of the event.
62. 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.

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

63. At least 7 days prior to the date on which planting of the GMOs is intended to commence at any Location, 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 (if any) are intended to commence;
  - (b) detail of the Location, including the street address or other directions, GPS coordinates and dimensions (in metres);
  - (c) whether the Location will be surrounded by a Pollen Trap or by a Monitoring Zone and an Exclusion Zone;
  - (d) the identity of the GMOs which are intended to be planted;
  - (e) the period during which the licence holder considers the GMOs and Pollen Trap Plants (if any) are likely to flower;
  - (f) the period during which the licence holder considers the GMOs are likely to be harvested;
  - (g) if GMOs have previously been planted at the 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 has been used in the preceding two years, including details of previous GMOs and post-Harvest crops planted; and
  - (h) a description of how the Location and Pollen Trap (if any) are intended to be used during the first year following the harvest of the GMOs.
64. Within 7 days of planting of the GMOs, the licence holder must provide a notice in writing to the Regulator which indicates the actual date(s) on which planting of the GMOs occurred and any changes in the details required to be provided under the immediately preceding condition.

### **Notice of harvest and Cleaning**

65. Within 14 days of commencement of harvesting of the GMOs at a Location, the licence holder must provide the actual date or dates of commencement of harvesting of the GMOs at a Location.

66. Within 14 days of the date on which Cleaning of an area requiring Cleaning is completed, the licence holder must provide a notice in writing to the Regulator indicating the date or dates on which Cleaning was undertaken.

67. On the request of the Regulator, the licence holder must provide written documentation of the procedures in place to ensure continuing compliance with the Cleaning conditions in this licence.

#### ***Notices of inspection activities***

68. The results of all inspection activities must be recorded in a Logbook and must contain at least the following:

- (a) the date(s) of inspection; and
- (b) the names of the person or persons who undertook the inspection; and
- (c) details of the experience, training or qualification that enables each person to recognise Volunteers, if not already recorded in the logbook; and
- (d) details of the areas inspected; and
- (e) details of current land use (e.g. type of crop being grown) and of recent land management practices (e.g. irrigation, cultivation or spraying) applied in the areas inspected; and
- (f) details of any post-harvest rainfall events at the Location including measurements of any rainfall at or near the Location; and
- (g) the means of inspection used; and
- (h) the number of Volunteers observed, if any; and
- (i) details of the development stages reached by the Volunteers, if any; and
- (j) details of methods used to Destroy Volunteers, if any, and the actual date(s) of Destruction, if different from the date of inspection; and
- (k) details of Cotton plants intentionally grown in the Exclusion Zone, if any, whilst the GMOs are growing.

69. The results of the inspections as recorded in the Logbook must be forwarded to the Regulator within 35 days of inspection taking place.

#### ***Extreme weather conditions***

70. The licence holder must immediately, by notice in writing, inform the Regulator of any extreme weather conditions such as cyclones or flooding that have affected or are expected to affect a Site whilst the GMOs are growing at the Site or whilst subject to inspection requirements.

#### ***Other records to be kept***

71. The licence holder must keep records of the types of GM Cotton grown at each Location as part of the trial, and the area planted to each type of GM Cotton.

#### ***Testing methodology***

72. Within 30 days of the date of issue of this licence, 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 in a recipient organism. The detection method must be capable of

reliably distinguishing between the genetic modifications described in Attachment A of this licence. The licence holder must provide additional testing information on the request of the Regulator.

**DIR No: 113**

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

**Organisation Details**

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

**Phone No:** (03) 9248 6888

**Fax:** (03) 9248 6800

**IBC Details**

**IBC Name:** Bayer CropScience IBC

**GMOs covered by this licence**

*Gossypium hirsutum* L. containing only the combinations of introduced genes and genetic elements listed below.

**Parent Organism:**

Common Name: Cotton

Scientific Name: *Gossypium hirsutum* L.

**Modified traits:**

Categories: Insect resistance  
Herbicide tolerance  
Selectable marker - antibiotic

Description: Cotton varieties have been genetically modified for insect resistance and herbicide tolerance. The plants contain different combinations of introduced *Bacillus thuringiensis* genes conferring insect resistance and introduced genes conferring herbicide tolerance. Some of the plants also contain an introduced antibiotic resistance selectable marker.

**Genetic elements responsible for conferring the modified traits:**

Details of the genes and other sequences inserted into the GM cotton varieties have been declared Confidential Commercial Information (CCI) under section 185 of the Act.

**Purpose of the dealings with the GMOs:**

The purpose of the field trial is to assess the agronomic performance of the GM cotton varieties under field conditions, and to produce seed for use in further studies or releases. The GM cotton is not permitted to enter human food or animal feed.