



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 101

Licence holder: Monsanto Australia Limited

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

Issued: 16 July 2010

Varied: 26 July 2011

Varied: 13 May 2013

Varied: 02 Sep 2013

Varied: 03 Sep 2013

Varied: 07 Mar 2014

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 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 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.

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 at

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir101>.

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 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* (Cth) or the corresponding State legislation under which this licence is issued.

'Clean' (or **'Cleaned'**), as the case requires, means:

- (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. and *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) uprooting ; or
- (b) ploughing; or
- (c) burning/incineration; or
- (d) treatment with herbicide; or
- (e) hand weeding; or
- (f) autoclaving; or

- (g) burial under at least 1 metre of soil; or
- (h) 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 harvesters, seeders, storage equipment, transport equipment (eg bags, containers, trucks), clothing and tools.

'Exclusion Zone' means an area extending at least 3 kilometres in all directions from the outer edge of a location, which must be kept free of deliberately planted (GM and non-GM) Cotton while the GMOs are growing in the 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 or glasshouse where the GMOs or other plants are 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 Regulator on request.

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

'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 under this licence to be inspected following harvest or destruction of the GMOs at a Location.

'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, other than lint obtained from ginning. This includes, but is not limited to, seed, stubble and pollen, whether from the plant itself (whether viable or not) 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, DIR 066/2006 or DIR 091 grown in a Pollen Trap.

'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 the aggregate of all Places in respect of any one Location.

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

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 Monsanto Australia 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

8. 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

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

Persons covered by this GMO licence

10. 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

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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

17. 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.

18. 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.

19. The licence holder must inform the Regulator, as soon as practically and reasonable possible, 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 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, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

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 and control all Locations, Sites, Monitoring Zones, approved facilities or other premises to the extent necessary to comply with this licence, for the duration of the life of the licence.

25. Where the licence holder does not have legal access and control of a Location, Site, Monitoring Zones, approved facility or other premise to the extent necessary to comply with this licence, for the duration of the life of the licence, then 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 a Location, Site, Monitoring Zones, approved facility or other premise 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 B.

Permitted dealings

28. The permitted dealings with the GMOs are to conduct experiments with the GMOs, breed, propagate, grow, culture, transport and dispose of the GMOs, use the GMO in the course of manufacture of a thing that is not a GMO, and the possession, supply and use of the GMOs in the course of any of these dealings.

Non-GM Plants and GM plants other than the GMO

29. Other than the GMOs, only non-GM Cotton and GM Cotton approved under licences DIR 062/2005, DIR 066/2006 or DIR 091 may be grown at a Location or Pollen Trap with respect to a Location, and Plant Material from these plants must be handled and controlled as if it were the GMOs or Plant Material from the GMOs.

Note: GM Cotton plants other than the GMOs must also be dealt with in accordance with the conditions of the relevant licences. For GM Cotton approved under DIR 091, planting is not authorised north of latitude 22° South.

Limits - Locations, growing season and size of trial

30. With respect to the permitted dealings described in condition 28, planting, propagating, growing, culturing and harvesting must only be undertaken between October 2010 and

October 2014, inclusive, within the local government areas (LGAs) listed in the immediately following table.

Queensland	New South Wales	Western Australia
Balonne Shire	Balranald Shire	Shire of Broome
Banana Shire	Bogan Shire	Shire of Wyndham-East Kimberley
Brisbane City	Bourke Shire	
Burdekin Shire	Carrathool Shire	
Central Highlands Regional	Central Darling Shire	
Western Downs Regional	Coonamble Shire	
Goondiwindi Regional	Gunnedah Shire	
Isaac Regional	Gwydir Shire	
Lockyer Valley Regional	Hay Shire	
Paroo Shire	Inverell Shire	
Roma Regional	Lachlan Shire	
Somerset Regional	Liverpool Plains Shire	
South Burnett Regional	Moree Plains Shire	
Toowoomba Regional	Narrabri Shire	
	Narromine Shire	
	Walgett Shire	
	Warren Shire	
	Warrumbungle Shire	

31. If a Location is a glasshouse it must be located at the Monsanto Biotechnology Research Centre, 3 Rocla Court, Toowoomba, Qld (LGA of Toowoomba Regional) or at the Department of Primary Industries Quarantine Facility, 160 Curtin Ave, West Eagle Farm, Qld (LGA of Brisbane City).
32. In the Brisbane City LGA, planting is only permitted in a glasshouse.
33. Intentional planting of the GMO must occur in no more than 50 Locations per season.
34. The maximum combined area of the 50 Locations must not exceed 50 hectares planted in the 2010/2011 season, 100 hectares planted in the 2011/2012 season, 500 hectares planted in the 2012/2013 season, and 500 hectares planted in the 2013/2014 season.
35. The maximum area per Location must not exceed 100 hectares.

Containment measures

36. If the Location is a glasshouse:
 - (a) the glasshouse must not be within 50 metres of a Natural Waterway; and
 - (b) the licence holder must either:
 - i. implement an insect control program (as provided to the Regulator) which effectively controls pollinating insects in the glasshouse while the GMOs are flowering; or
 - ii. the glasshouse must not be within 3 km of intentionally field planted Cotton; and
 - (c) access to the glasshouse must be restricted to the licence holder and persons covered by the licence; and
 - (d) details of the implementation of the insect control program, if used, must be made available to the Regulator upon request.
37. Each Location (with the exception of a glasshouse) must be:
 - (a) surrounded by a Monitoring Zone and an Exclusion Zone; or
 - (b) surrounded by a Pollen Trap.

38. If a Monitoring Zone and an Exclusion Zone are used in accordance with the immediately preceding condition:
- (a) the outer edge of the Location must not be within 50 metres of a Natural Waterway; and
 - (b) while the GMOs are being grown at the Location, the Monitoring Zone must be inspected every 30 days, and any Cotton plants in the Monitoring Zone Destroyed prior to Flowering; and
 - (c) if any Cotton is intentionally planted within the Exclusion zone while the GMOs are being grown at the Location other than pursuant to this licence, either the intentionally planted Cotton or the GMOs in the Location must be Destroyed prior to Flowering. If GMOs are Destroyed pursuant to this condition, the GMOs are taken to have been harvested for the purposes of this licence and all conditions applying to post-harvest apply equally to post-Destruction.
39. If a Pollen Trap surrounds a Location:
- (a) the outer edge of the Pollen Trap must not be within 50 metres of a Natural 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.

Section 4 Use of Plant Material

Note: Cotton lint obtained from ginning is not subject to these conditions.

Plant Material not to be used in food or animal feed

40. 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 humans or feed for animals.

Experimentation and storage

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

- (a) within a Location or Pollen Trap; or
- (b) within the following facilities that are signed so as to indicate that GM Plant Material is present within the facility:
 - i. the Monsanto Biotechnology Research Laboratory at 3 Rocla Court Harlaxton, Toowoomba, Qld, 4350; or
 - ii. the Monsanto Narrabri Laboratory “Locharba” at 21149 Kamilaroi Highway, Narrabri, NSW, 2390; or

- iii. a facility approved in writing by the Regulator.

Note: This licence does not expressly authorise or prohibit any dealings or storage in certified physical contained facilities. Under the Act it is not on offence to deal with a GMO if the dealing is otherwise licensed or if it is an NLRD or an exempt dealing and it complies with all relevant statutory requirements.

42. Plant Material used for experimentation or analysis must be either be stored or Destroyed as soon as practicable after use.

43. Plant Material may be stored off Site in a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is stored within the facility. Stored Plant Material must be contained within a sealed, unbreakable container that is clearly labelled so as to indicate the contents

43A. Cotton modules or bales may be stored on the Site for up to 6 months post-Harvest provided that:

- i. all exposed sides of cotton modules and bales are completely covered by durable tarpaulin or plastic to minimise dispersal of GMOs in the environment; and
- ii. the cotton modules or bales are labelled clearly so as to indicate their contents; and
- iii. the cotton modules or bales are not stored in an area that is prone to flooding or heavy runoff after rainfall.

Note that the area used to store modules or bales and the covering of the modules or bales are subject to other licence conditions with regard to cleaning, inspection and sign-off.

43B. Any plant material not stored as authorised by conditions 43 and 43A must be stored 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 storage.

Transportation of Plant Material

44. Plant Material may only be transported to the extent necessary to store it, Destroy it, Clean it from equipment, gin it, export it, conduct experiments or analysis on it, transfer it to a Location or relocate it for the purpose of conducting dealings pursuant to another relevant authorisation under the Act.

45. Subject to the immediately following condition, any Plant Material transported outside a Site must be transported in accordance with the Regulator's *Guidelines for the Transport of GMOs* as current at the time of transportation.

46. If harvested Plant Material is transported in a cotton module or bale, the routes and procedures used for this transportation must be documented and provided to the Regulator on request, and the cotton modules or bales 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 or a taut liner truck specifically designed for the purpose of transporting cotton modules or bales, respectively; and

- (d) labelled as detailed in the Regulator's *Guidelines for the Transport of GMOs* as current at the time of transportation.

Section 5 Harvest, Cleaning and Disposal

47. If GMOs growing 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.
48. If the GMOs or non-GM plants grown at a Location or Pollen Trap Plants are harvested, they must be harvested separately from any other crop.
49. If seed Cotton harvested from the GMOs or non-GM plants grown at a Location or Pollen Trap Plants is ginned, it must be ginned separately from any other crop.
50. Cleaning of Equipment used in conjunction with the GMOs must occur as soon as practicable after use and before it is used for any other purpose, so as to prevent dispersal of viable Plant Material

Note: For example if GM seed is ginned, the gin must be Cleaned immediately following its use and before any other Cotton crop is ginned, or if a harvester is used it must be Cleaned before it is moved to another field.

51. The following areas must be Cleaned either within 28 days of Harvest or within 9 months of planting of the GMOs at a Location, whichever occurs first:
- (a) the Location; and
 - (b) the Pollen Trap (if any) in respect of the Location; and
 - (c) any areas onto which Plant Material was dispersed during harvest of the GMOs at the Location, packing for transport after harvest, or storage of bales/modules; and
 - (d) any areas used to Clean Equipment used at the Location; and
 - (e) any other areas used to Destroy Plant Material in the vicinity of the Location.

51A. Any portion of a Site used for storage of modules or bales under condition 43A is exempt from the immediately preceding condition until such time as the module or bale is destroyed or removed.

52. The following areas must be Cleaned as soon as practicable after use so as to prevent the spread and persistence of the GMO:
- (a) any areas used to gin Plant Material; and
 - (b) any facilities used to store or to experiment on Plant Material.

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

Section 6 Conditions on use of Locations and other Places after harvest

General conditions on use of Places post-harvest

53. After harvest of the GMOs at a Location, no plants may be intentionally grown in a Place in respect of that Location 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 non-GM 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 relevant Site.

Cotton seed bank reduction

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

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

54A. Cotton modules or bales stored on the Location or Pollen Trap under condition 43A must be destroyed or removed prior to undertaking the Cultivation required in the immediately preceding condition.

Section 7 Inspections

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

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

Post-Cleaning inspections

56. Following Cleaning of a Location, the following are Places that must be inspected for the existence of Volunteers:

- (a) the Location (except for glasshouses);
- (b) the Pollen Trap, if any;
- (c) irrigation channels and drains through which water flows to and from the Location (except for glasshouses) and the Pollen Trap, if any;
- (d) any areas in which Volunteers may be able to establish, including, but not limited to areas:
 - i. that were used to Clean Equipment used in connection with Plant Material; or
 - ii. onto which Plant Material was dispersed during harvesting, packing for transport or storage of bales/modules; or
 - iii. that were used to Destroy Plant Material.

57. For each Location, all Places must be inspected at least once every 2 months, commencing on the last day of Cleaning of the Location and continuing until:

- (a) the Place is replanted to the GMOs; or
- (b) the Regulator has issued a Sign-off for the relevant Site.

58. Any Volunteers must be Destroyed prior to Flowering.

58A. Modules or bales stored under condition 43A must be inspected for damage to the tarpaulin or plastic covering and for any evidence of dispersal of the GMO, at least once every 30 days and continuing until the module or bale is destroyed or removed.

59. 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.

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

Sign off

60. For Sites in which the associated Location is a glasshouse, the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site once the Location and other areas requiring Cleaning have been Cleaned, and there are no Places in respect of the Location requiring inspections.

61. For all other Sites, if:

- (a) inspections have been routinely completed for a period of at least 12 months; and
- (b) inspection records for that Site show that no Volunteers have been observed in the most recent 6 month inspection period; and
- (c) modules or bales have not been stored on the Site in the most recent 6 month inspection period

the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site.

Note: Licence conditions require Cultivation for each Location (other than a glasshouse) and Pollen Trap, if any, prior to a Sign-off application (see Section 6 – Conditions on use of Locations and other Places after Harvest). The Regulator will take into account the management and inspection history for the Site, including tillage, irrigation, 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

62. 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.

63. 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) 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.

64. 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, planting and Flowering

65. For all Locations other than glasshouses, at least 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 (if any) are intended to commence;
- (b) details of each Location where the GMOs will be planted, including if the area has been previously used under this licence, the size of each Location, the local government area, a map of the Location and its surroundings, a street address and GPS coordinates for each Location;
- (c) whether the Location will be surrounded by a Pollen Trap or by 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 likely to be harvested (or Destroyed in lieu of harvest);
- (g) 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 has 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;
- (h) a description of how the Location is intended to be used during the first year following the harvest of the GMOs; and

66. For the glasshouse Locations, at least 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 are intended to commence; and
- (b) the address of the glasshouse; and
- (c) the identity of the GMOs which are intended to be planted; and
- (d) the period during which the licence holder considers the GMOs likely to be harvested (or Destroyed in lieu of harvest).

67. For all Locations, 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 preceding two conditions.

Notice of harvest and Cleaning

71. Within 7 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.

72. 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.

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

Notices of inspection activities

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

- (a) details of the experience, training or qualification that enables each person to recognise Volunteers, if not already recorded in the logbook;
- (b) the date(s) of inspection;
- (c) the names of the person or persons who undertook the monitoring;
- (d) details of the areas inspected;
- (e) details of current land use (eg type of crop being grown) and of recent land management practices (eg irrigation, cultivation or spraying) applied in the areas inspected;
- (f) details of any rainfall events at the Location, including measurements of any rainfall at or near the Location;
- (g) the number of Volunteers observed, if any;
- (h) details of the development stages reached by the Volunteers, if any;
- (i) details of methods used to Destroy Volunteers, if any; and the actual date(s) of Destruction, if different from the date of inspection; and
- (j) details of any repairs to tarpaulins or plastic coverings of modules or bales.

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

Other records to be kept

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

Extreme weather conditions

77. The licence holder must immediately, by notice in writing, inform the Regulator of any extreme weather conditions such as strong winds or flooding that have affected a Site whilst the GMO is growing at a Location and until the Site is Cleaned; and whilst modules or bales are stored on a Site, noting any movement of GM material off site.

Note: The Contingency Plan must be implemented in the event that the GMO or Plant material is moved off site, as per condition 64.

Testing methodology

78. 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 GMOs described in this licence and those described in other licences. The instrument must be provided within 30 days of the issuing of this licence.

ATTACHMENT A

DIR No: 101

Full Title:

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

Organisation Details

Postal address:

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

IBC Details

IBC Name:

Monsanto Australia Ltd IBC

GMO Description

GMOs covered by this licence:

Gossypium hirsutum L. containing only the genes, the marker genes and the genetic elements listed below.

Parent Organism:

Common Name: Cotton

Scientific Names: *Gossypium hirsutum* L.

Modified traits:

Categories: Insect resistance
Herbicide tolerance
Antibiotic resistance
Selectable marker

Description: Bollgard III and Bollgard III/Roundup Ready Flex[®] cotton plants have been genetically modified for insect resistance either alone or in combination with herbicide tolerance. The plants also contain antibiotic resistance and other selectable markers. These GM cottons are generated by conventional breeding of commercially licensed GM Bollgard II[®] cotton (containing *cry1Ac* and *cry2Ab* genes) or GM Bollgard II[®]/Roundup Ready Flex[®] cotton (containing *cry1Ac* and *cry2Ab* genes and two copies of the *cp4 epsps* gene) with another GM cotton, VIP3 cotton (containing the *vip3A* gene). Any GM segregants of Bollgard III and Bollgard III/Roundup Ready Flex[®] cotton not covered by a commercial licence is covered by this licence.

Genetic elements responsible for conferring the modified traits:

two copies of *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 (herbicide tolerance)
cry1Ac and *cry2Ab* genes from the bacterium *Bacillus thuringiensis* (insect resistance)
nptII gene from the bacterial Tn5 transposon (antibiotic resistance)
uidA gene from the bacterium *Escherichia coli* (reporter gene)
vip3A gene from *Bacillus thuringiensis* (insect resistance)
aph4 gene from *Escherichia coli* (antibiotic resistance)

Purpose of the dealings with the GMOs:

Monsanto applied for a licence for dealings involving the intentional release of two GM cottons (Bollgard III and Bollgard III/Roundup Ready Flex[®]) on a limited scale and under controlled conditions.

The purpose of the trial is to generate data for future submissions to regulatory agencies, to breed and develop varieties using elite germplasm suitable for use under Australian conditions, and for seed increase.